Sysmex

OPERATOR'S MANUAL

AUTOMATED HEMATOLOGY ANALYZER

SF-3000

SYSMEX CORPORATION
KOBE, JAPAN

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Code No. 461-2459-3
PRINTED IN JAPAN
Date of Last Revision: March 2001

SF-3000/06.95

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RECEIVING INSTRUCTIONS

The SF-3000 has been thoroughly tested before shipment, and has been packaged carefully to prevent damage from shipping and handling. Reagents and options have also been sent and will arrive at approximately the same time as the analyzer. Follow these guidelines when the system arrives:

- Check to see that the arrows on the sides of the packages are pointing up. If the arrows do not point up, remark this information on the bill of lading.
- Visually inspect the outside of the package for rips, dents, or possible shipping damage. Document any sign of damage on the bill of lading, regardless of how insignificant it may appear. *This is for your protection!*
- Notify your service representative that the SF-3000 system and its components have arrived.
- Wait for your service representative to unpack the system and open the packages.
- Follow the unpacking and storage instructions provided on the outside of the package. Special requirements such as refrigeration are clearly marked on the outside of the carton and will be included in the unpacking instructions and package inserts.

WARRANTY INFORMATION

All instruments manufactured by Sysmex® are warranted against defective materials or workmanship for a period of one year commencing on the installation date at the customer's required location.

This Warranty does not cover any defect, malfunction, or damage due to:

1. Accident, neglect or willful mistreatment of the product
2. Failure to use, operate, service, or maintain the product in accordance with the applicable Sysmex Operator's Manual
3. Failure to use the appropriate reagents or chemicals specified for the product

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1. INTRODUCTION

The Sysmex® SF-3000 is a technically advanced, computerized, fully automated hematology analyzer with many features, for **in vitro diagnostic** use in clinical laboratories. The SF-3000 provides accurate screening for patients whose hematological abnormalities indicate the need for further testing. In addition, it can contribute in the diagnosis and therapeutic monitoring of patients.

The SF-3000 has the capability of analyzing up to 80 samples per hour, and display 4 different patterns -- WBC 5 differential, scattergrams for white blood cells and basophils, and cell size distribution curves for red blood cells and platelets, as well as 23 analysis data parameters on the color LCD (liquid crystal display) screen.

Chapter 1 is an introduction to this manual, major system components, system operation and other general considerations. This chapter should be read before operating the SF-3000. Chapter 1 contains the following subjects:

Manual Organization
A description of the Operator's Manual and explanation of important informational headings.

System Overview
An introduction to the main elements of the SF-3000 analyzer, including a description of the options available to enhance the instrument's operation.

Safety Summary
Covers major safety considerations when using and servicing the SF-3000.

Operational Summary
A summary of the operating procedures for each mode, the LCD screen display, functions of touch panel, etc.

Installation Requirements
Includes space requirements, necessary equipment, installation environment and other essential information to be reviewed before installation of the SF-3000.

Instrument Specifications
The instrument's specifications are given in a reference table.

2. OPERATOR'S MANUAL ORGANIZATION

The SF-3000 Operator's Manual has been designed with the operator in mind. Each chapter has its own table of contents and is designed to facilitate rapid location of appropriate information.

Table 1-1: Manual Organization

CHAPTER 1 Introduction	Contains basic information about the instrument; operating procedures, screen displays, touch panel, installation and safety. This chapter must be read prior to operating the Sysmex SF-3000.
CHAPTER 2 Sample Processing	Explains sampling procedure from start-up to shutdown. All sampling operation procedures are contained in this chapter.
CHAPTER 3 Work List	Explains how to enter order information with the display and management of the records.
CHAPTER 4 Result Interpretation/ Reports	Explains procedures for displaying and processing Stored Data, and procedures for analyzed result output. Also explains IP messages.
CHAPTER 5 Maintenance and Supplies	Explains periodic maintenance, and the procedures for replacing consumables and reagents.
CHAPTER 6 Quality Control	Explains how to run the Quality Control Program. Also explains, for your reference, the quality control system used in this instrument.
CHAPTER 7 Calibration	Explains the procedures for auto-calibration and manual calibration.
CHAPTER 8 Troubleshooting	Explains error messages and their troubleshooting. Also explains service data and system test functions.
CHAPTER 9 Adjustments	Explains how to adjust pressure and other adjustments.
CHAPTER 10 Functional Descriptions	Gives the main principles of analysis performed by the instrument. Also contains system nomenclature.
CHAPTER 11 System Setup	Explains how to set date, time, units, sample analysis stop and other system conditions. Also contains data analysis settings -- for abnormal data judgments, etc.
APPENDICES A, B, C Menu Tree, Installation and Technical Information	Contains program menu tree, technical information including unpacking check lists, installation procedures, bar-code labeling parameters and host communication protocols.

3. INFORMATIONAL HEADINGS

3.1 NOTE, CAUTION and WARNING

NOTE, CAUTION and WARNING boxes throughout this manual are meant to get to attention to important safety and operational information. Always follow the instructions contained in the boxes. Failure to do so may affect the safety or precision features of the SF-3000 analyzer. The boxes are defined as follows:

NOTE:	Highlights important facts, gives helpful information, and clarifies procedures.

CAUTION:	Provides information on the correct operation of the SF-3000 analyzer. Information contained in CAUTION boxes is crucial to prevent damage and to maintain performance of the analyzer.

WARNING!	Indicates potentially hazardous situations that could result in serious injury or infection to laboratory personnel.

3.2 Document Conventions

The SF-3000 Operator's Manual uses the following conventions:

"Quotations": Screen commands, messages, and status information that the SF-3000 system displays appear within quotation marks. For example:

"All Samples", "Ready" or "Input Password"

[Square Brackets]: Names of function keys such as control or operational keys, number keys, or arrow keys that you select on the SF-3000 appear within square brackets. For example:

[Enter], [Sampler], [2] or [↑]

Italics: Application names and reference material appear in italic form. For example:

Refer to *Chapter 2: Sample Processing.*

4. SYSTEM OVERVIEW

The purpose of the SF-3000 is to provide accurate results on 23 parameters and to detect abnormalities in the sample. To assist the laboratory in the screening of abnormalities, the SF-3000 analyzes and processes the data obtained from the analyzer unit, and the LCD displays and outputs either a POSITIVE or a NEGATIVE message for each sample. A NEGATIVE message signifies that parameter values for the sample are within acceptable limits and the sample does not require any additional verification of those values. A POSITIVE message signifies that the sample is not within the acceptable limits and requires further review and investigation. Proper use of the instrument requires each laboratory to establish the acceptable limits for results.

The SF-3000 uses the optical detector block incorporating the semiconductor laser to analyze the WBC population. In the DIFF channel, lymphocytes, monocytes, eosinophils, and the group of neutrophils and basophils are analyzed to determine the WBC 4-differentials using flow cytometry. Basophil determination and WBC number counting are performed in the BASO channel. RBCs and PLTs are analyzed by the RBC detector block using the DC detection method. HGB determination is performed using the SLS hemoglobin detection method.

The SF-3000 consists of two major systems.

- Main Unit : Houses the hydraulic and electronic systems and their control components. The unit analyzes, processes and displays the data on the LCD screen.
- Pneumatic Unit : Supplies the required pressure and vacuum for analysis.

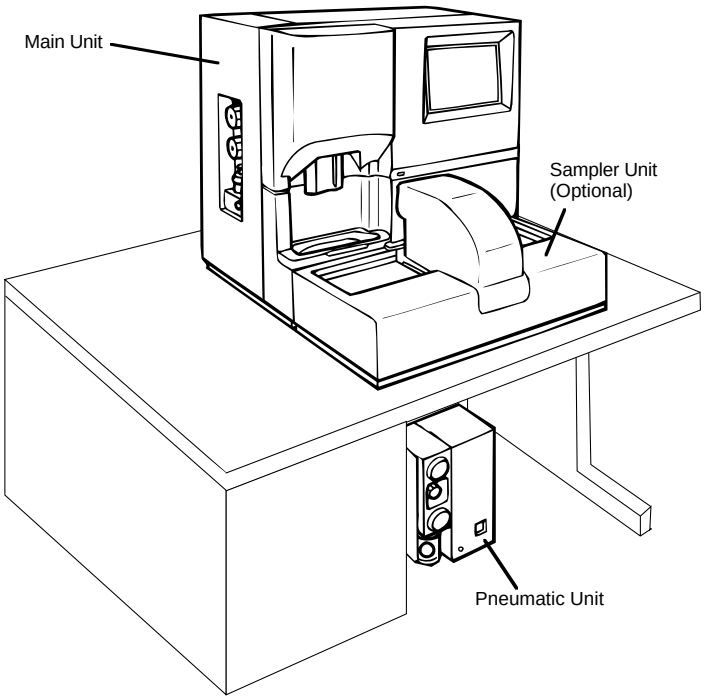

Figure 1-1: Sysmex SF-3000 Hematology Analyzer

5. SYSTEM OPTIONS

Several options are available to enhance system efficiency. Available options for the SF-3000 are:

- ID Bar Code Reader : Reads the ID numbers of bar code labeled samples, and inputs the numbers automatically.
- Color Graphics Printer or Page Printer : Prints out analysis results (cell size distribution graphs, scattergrams) and hard copies of screens in color or black and white.
  Printing can be done both in graphic and list format.
- Data Printer : Prints the analysis data in ticket format.
- (Cap Piercing) Sampler Unit : Consists of a mixer and a cap piercer unit, and loads up to 5 sample racks (50 sample tubes) that enable an automated closed sampling system.
- Manual CP Unit : Consists of a mixer and a cap piercer unit which enables a manual closed sampling system.

6. SAFETY

The operator must follow the instructions in this section. It contains important information to operate the SF-3000 analyzer safely.

6.1 General Safety

While operating, maintaining, servicing or repairing the system, follow all procedures contained in this manual. The operator must observe all NOTES, CAUTIONS and WARNINGS posted anywhere on the instrument or given in this manual.

Do NOT touch the electrical circuits behind the enclosure panels of the SF-3000. Touching the circuits is dangerous and may give you an electrical shock, especially if your hands are wet.

Use only designated tools and parts for service and repair. Substitute parts should never be used, and the SF-3000 should not be modified in any way.

Keep hair, clothing and fingers away from all moving parts.

Install the Sampler Unit on a table or work bench to prevent the system from accidentally falling.

6.2 Hazardous and Biohazardous Material

All surfaces and components in contact or potentially in contact with patient blood samples should be considered contaminated. Use of protective garments and gloves is strongly recommended when operating, maintaining, or servicing the SF-3000.

Do not touch the waste when disposing of it or assembling/disassembling the associated parts. If accidental contact with waste or any other potentially biohazardous material occurs, flush the affected area immediately with water and follow your laboratory's prescribed cleaning and decontamination procedures.

Consider all regulations applicable to your laboratory when operating the Sysmex SF-3000 instrument.

6.3 Reagent Safety

If reagent comes into contact with skin or clothing, flush it with water. If eyes are affected, flush with copious amounts of water and obtain medical advice if necessary.

6.4 Laser Safety

The SF-3000 uses a semiconductor laser unit. Though this laser unit is placed in the shield box, the operator must observe all NOTES, CAUTIONS and WARNINGS concerning laser handling.

WARNING!: DO NOT remove the shield box cover of the Laser Unit.

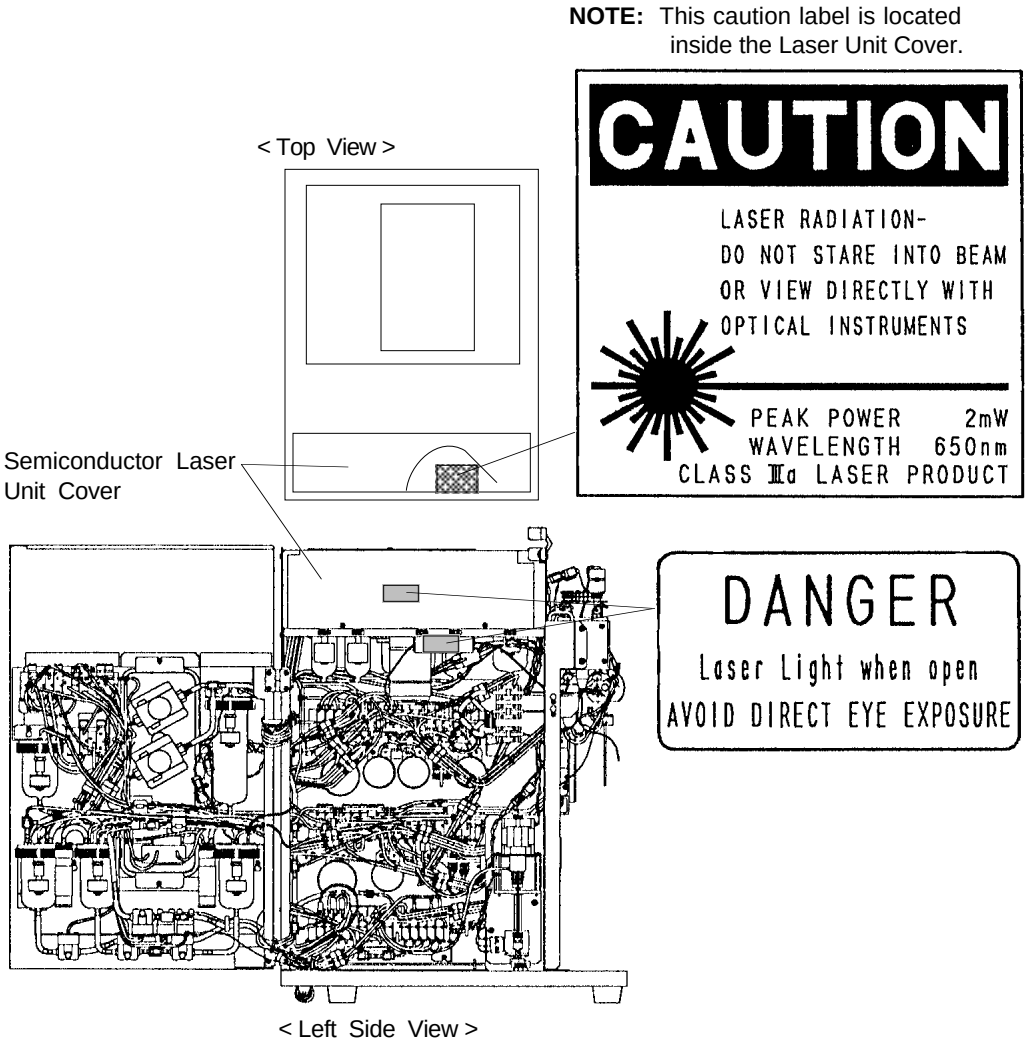

Figure 1-2: Location of Laser Unit and Labels (Left Interior of the Main Unit)

Refer to *Chapter 5, Section 6* for further information on laser handling.

7. OPERATIONAL SUMMARY

The SF-3000 has two basic operating modes: the Manual Open Mode and Capillary Mode. Additional three operating modes are available by means of optional units: the Sampler Mode and Manual Closed Mode by means of Cap Piercing Sampler Unit, and Manual CP Mode by means of Manual CP Unit.

Table 1-2: Operation Modes

<table>
<tr><td>Manual Open Mode</td><td>Capillary Mode</td><td>Sampler Mode</td><td>Manual Closed Mode</td><td>Manual CP Mode</td></tr>
<tr><td colspan="5">Operator checks</td></tr>
<tr><td colspan="5">Turn ON power</td></tr>
<tr><td colspan="5">Self-check
Auto rinse</td></tr>
<tr><td colspan="5">Ready</td></tr>
<tr><td>Select manual mode</td><td>Select capillary mode</td><td>Press [Sampler]</td><td>Select closed mode</td><td>Select closed mode</td></tr>
<tr><td rowspan="2">Set manual sample ID</td><td>Prepare capillary analysis sample (1:5 dilution)</td><td rowspan="2">Set sample ID (or read bar code label)

Set rack No.
Set tube No.</td><td rowspan="2">Set closed sample ID</td><td rowspan="2">Set closed sample ID</td></tr>
<tr><td>Set capillary sample ID</td></tr>
<tr><td colspan="2" rowspan="2">Set sample at manual aspiration pipette</td><td colspan="2">Place sample in rack</td><td rowspan="2">Place sample in Manual CP Unit</td></tr>
<tr><td colspan="2">Set rack on sampler</td></tr>
<tr><td colspan="2">Press the Start Switch</td><td>Press [Start]</td><td>Press the Start Switch</td><td>Press the Start Switch</td></tr>
<tr><td colspan="5">Analysis performed
Analysis complete</td></tr>
<tr><td colspan="5">Post-analysis check</td></tr>
<tr><td colspan="5">Perform shutdown</td></tr>
<tr><td colspan="5">Power OFF</td></tr>
</table>

Operations performed by the operator are indicated in **bold** print.

Ready: READY LED turns on and "Ready" message is displayed on the LCD screen. In this state, various operations can be performed, including analysis setting and data processing.

8. ANALYSIS PARAMETERS

The SF-3000 uses 4 detection methods and 5 types of reagents to analyze the following 23 parameters:

Table 1-3: Analysis Parameters

Parameter	Acronym	Detection Method
White Blood Cell Count	WBC	Flow Cytometry by Semiconductor Laser
Red Blood Cell Count	RBC	DC
Hemoglobin Concentration	HGB	SLS hemoglobin
Hematocrit (true relative percentage volume of erythrocytes)	HCT	RBC Cumulative Pulse Height Detection
Mean Corpuscular (erythrocyte) Volume	MCV	Computed from RBC and HCT
Mean Corpuscular Hemoglobin	MCH	Computed from RBC and HGB
Mean Corpuscular Hemoglobin Concentration	MCHC	Computed from HCT and HGB
Platelet Count	PLT	DC
Neutrophil Percent	NEUT%	Flow Cytometry by Semiconductor Laser
Lymphocyte Percent	LYMPH%	
Monocyte Percent	MONO%	
Eosinophil Percent	EO%	
Basophil Percent	BASO%	
Neutrophil Count	NEUT#	Flow Cytometry by Semiconductor Laser
Lymphocyte Count	LYMPH#	
Monocyte Count	MONO#	
Eosinophil Count	EO#	
Basophil Count	BASO#	
RBC Distribution Width	RDW-SD	Computed
RBC Distribution Width	RDW-CV	Computed
Platelet Distribution Width	PDW	Computed
Mean Platelet Volume	MPV	Computed
Platelet Large Cell Ratio	P-LCR	Computed

NOTE: *Customers in the United States:* Platelet Distribution Width (PDW) and Platelet Large Cell Ratio (P-LCR) parameters have not been approved for reporting by the Food & Drug Administration (FDA). The obtained values should be excluded from all print forms until reporting approval has been obtained. See *Chapter 11* for information on excluding these values.

9. DISPLAY SCREEN

9.1 LCD (Liquid Crystal Display) Screen

The LCD screen is divided into 3 parts: the System Status Area, the Data Processing Area, and the Menu Area.

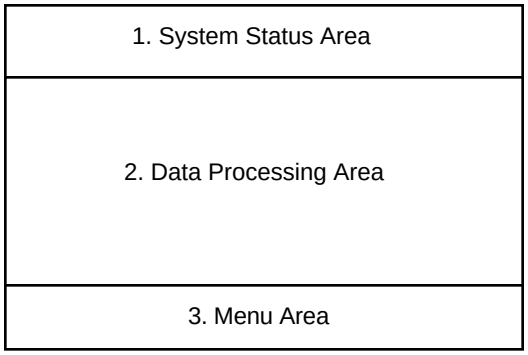

Figure 1-3: Display Screen

1. System Status Area

The System Status Area appears as the top two lines of the screen (Figure 1-4). This area displays Main Unit status information such as analysis status, errors, etc. It also displays data processing status information such as Peripherals, $\overline{X}$ M, etc. The [Sysmex] and [Sampler] function keys also appear in this area.

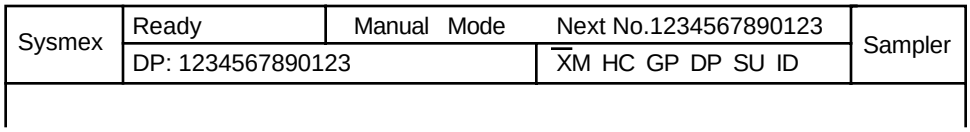

Figure 1-4: System Status Area

- **Analysis Status**

System status -- "Ready", "Not Ready", etc. is displayed to the left of the top line.

Analysis mode and the next sample ID number --

Analysis mode in which the system is set, and the next sample number to be analyzed in the selected analysis mode are displayed.
Pressing this keypad displays the Sample No. Setting Screen for the Open Sampling, Closed Sampling, or Capillary Sampling Manual mode. Using this setting screen, the analysis mode, next sample ID number for the selected analysis mode can be set up.
When the Capillary mode is selected, this area is displayed in yellow back-light.

NOTE: To set the next Sample ID No., Rack No. and Tube Position No. to be analyzed in the auto mode by means of Sampler Unit, press [Sampler] keypad to display the auto mode setting window.

The DP No. is displayed below the system status. If the Data Printer (DP) is the selected output device, the DP No. displayed indicates the next sample data number to be printed out.

Errors -- "2.0 kg/cm^2 Error", "Rack Move Error", etc. is displayed below the system status, in place of the DP No. If 2 or more errors occur simultaneously, they are displayed in order of importance. When an error is displayed, press [Sysmex] key to display the action/help messages provided in the Error Log program. Refer to *Chapter 8: Troubleshooting* for the action message display.

- **Data Processing Status**

$\overline{X}$ M : Indicates the status of $\overline{X}$ M control (one file of the QC program) in the following way:

No indication	:	$\overline{X}$ M control is not in use (Stop).
$\overline{X}$ M	:	$\overline{X}$ M control is in use (Start).
$\overline{X}$ M (with red back-light)	:	$\overline{X}$ M Limit Error has occurred.

HC : Indicates transmission status of data to the Host Computer.

No indication	:	The Host Computer is set to "Not Connected".
HC	:	Ready for transmission to Host Computer.
HC (with green back-light)	:	Now transmitting to Host Computer.
HC (with red back-light)	:	Transmission to Host Computer not occurring because of abnormality in Host Computer.
HC (with yellow back-light)	:	Error ("Not Transmissible", "No Ack" or "Ack Code Err") has occurred between SF-3000 and Host Computer.

GP : Indicates the status of the Graphic Printer (or Line Printer).

No indication	:	The Graphic Printer is set to "Not Connected".
GP	:	The Graphic Printer is ready.
GP (with green back-light)	:	Data being output to Graphic Printer.
GP (with red back-light)	:	Printing not possible because of abnormality in Graphic Printer.

DP : Indicates the status of the Data Printer.

No indication	:	The Data Printer is set to "Not Connected".
DP	:	The Data Printer is ready.
DP (with green back-light)	:	Data being output to Data Printer.
DP (with red back-light)	:	Printing not possible because of abnormality in Data Printer.

SU : Indicates the status of the Sampler Unit.

No indication	: The Sampler Unit is not connected.
SU	: Sampler Unit ready for sampler analysis.
SU (with red back-light)	: Sampler not operational because of abnormality in Sampler Unit.

CP : Indicates the status of the Manual Cap Piercing (CP) Unit.

No indication	: The Manual CP Unit is not connected.
CP	: Manual CP Unit ready for manual closed mode analysis.
CP (with red back-light)	: Manual closed mode not operational because of abnormality in Manual CP Unit.

ID : Indicates the status of the ID Bar Code Reader.

No indication	: The Bar Code Reader is set to "Not Connected".
ID	: The Bar Code Reader is ready.
ID (with red back-light)	: "ID Unit Com. Error" has occurred between SF-3000 and Bar Code Reader.

HD (with green backlight) : Appears when the system hard disk is being accessed.

- **Function Keys**

The [Sysmex] and [Sampler] keypads appear at each end of this area.

[Sysmex] -- Press this key to obtain the hard copy of screen and to access the Error Log. Refer to *Section 9.3* in this chapter for hard copy output. Refer to *Chapter 8: Troubleshooting* for Error Log.
When an error occurs, this key changes to [Alarm Reset] with red backlight. Press to stop the alarm.

[Sampler] -- Press to display the sampler start check window, where the Sample ID No., Rack No. and Tube Position No. for the next auto mode analysis can be set up. This keypad changes to [Sampler Stop] during auto mode analysis.

2. Data Processing Area

Analysis and sample information, including analysis data, scattergrams, cell size distributions, QC menus, action messages, sub-program menu keypads, etc. are displayed in the center area of the display screen.

3. Menu Area

The available menu choices are displayed in the bottom line of the display screen. Touch the desired keypad on the LCD to access and proceed for the program. In the Main Screen, the Root Menus appear in this area. Refer to *Section 9.2* in this chapter for the root menus.

NOTE: The program keys masked as shown below do not function when pressed.

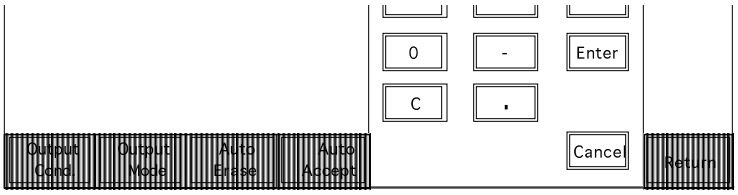

Figure 1-5: Example of Masked Program Keys

4. Power Saving Function

The LCD contrast will automatically decrease for the LCD power saving if the Main Unit does not detect any key operation on the LCD for 5 minutes. Touch anywhere on the LCD to exit the power saving mode.

9.2 Root Menus

When the instrument power is ON, the Main Screen with the Root Menus is displayed as the initial screen. By pressing the [Return] key on any screen, the visible display returns to the previous screen, finally to the Main Screen.
The SF-3000 provides twelve Root Menus. The Main Screen displays seven Root Menus on the menu line at a time. When you want to change a menu, press the [More] key to alternate root menu.

The Root Menus is listed below. Each Root Menu consists a second menu(s) or menu choices to proceed for the corresponding program.

[Status]
Use this menu to check the analyzer condition, analysis process, sensor status, etc. at any time. (This menu does not display analysis errors.)

[Work List]
Use this menu to display, register, and process the analysis information, including Sample No., Rack No., Tube Position, Order Information, etc. Refer to *Chapter 3: Work List* for more information.

[Stored Data]
This menu provides options to display analysis results up to 1,000 samples stored in the memory. The Stored Data List includes Date and Time analyzed, Sequential No., Sample No., Rack No., Tube Position, output status to the peripherals, flag information and analysis results. Refer to *Chapter 4: Result Interpretation/Reports* for more information.

[QC]
The SF-3000 quality control program provides $\overline{X}$ or L-J, and $\overline{X}$ M control applications. The QC Root Menu performs QC analysis, displays and/or outputs the QC Chart, establishes the QC settings, etc. Refer to *Chapter 6: Quality Control* for more information.

[GP Print]
Use this menu to get options to output the data currently displayed on the screen to the Graphic Printer.

[DP Print]
Use this menu to get options to output the data currently displayed on the screen to the Data Printer.

[Replace Reagent]
Use this menu after replacing a reagent container to prime the reagent into internal reservoir chamber.

[Mainte.]
Use this menu to perform the customer maintenance programs, such as waste chamber cleaning, clog removal, etc. and to perform the system test programs.

[Settings]
Use this menu to set the system parameters and conditions, such as date, time, units, analysis stop condition, etc. Also this program contains data analysis settings to establish certain standards for the SF-3000 system. System's operational parameters can be set up to meet individual laboratory preferences to customize the operation of the SF-3000. Refer to *Chapter 11: System Setup* for the setup procedure.

[Calib.]
Use this menu to calibrate the SF-3000 for specified parameter(s) automatically or manually. Refer to *Chapter 7: Calibration* for the procedure.

[Shutdown]
Use this menu to clean the detector chambers and all hydraulic lines in the SF-3000 system with detergent.

[Auto Rinse]
Use this menu to rinse the hydraulic lines with the diluents, and check the background values after rinsing. If the background values exceed the preset limit values, a "Background Error" occurs.

9.3 Hard Copy

The [Sysmex] keypad always appears on the left of the top line of the screen. Press this key to display the Sysmex submenu window as shown in Figure 1-6.

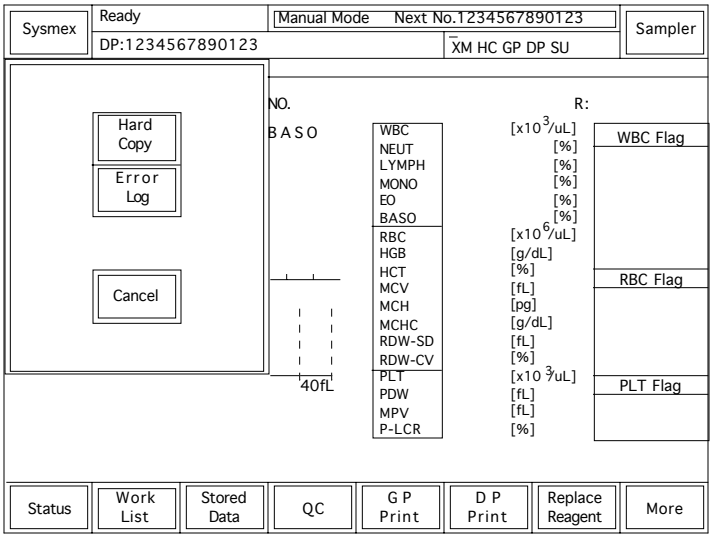

Figure 1-6: Sysmex Submenu Window

[Hard Copy]
Pressing this key outputs the hard copy of screen (screen shot), as displayed on the LCD at the time of pressing the [Hard Copy] keypad, to the Graphic Printer. This function is available in any status of instrument operation. The window will close automatically after pressing this key.

[Error Log]
Pressing this key displays the error log and action/help messages for a specified error. Refer to *Chapter 8: Troubleshooting.*

[Cancel]
Pressing this key closes the Sysmex submenu window.

10. PASSWORD

Some programs in Q.C., Settings and Calibration require a password entry to prevent unauthorized changes of the important settings and values. When such a program is selected, the Password Input Screen appears with the message "Input Password". Enter the registered password and press the [Enter] key. If the entered password is correct, the program will be executed.

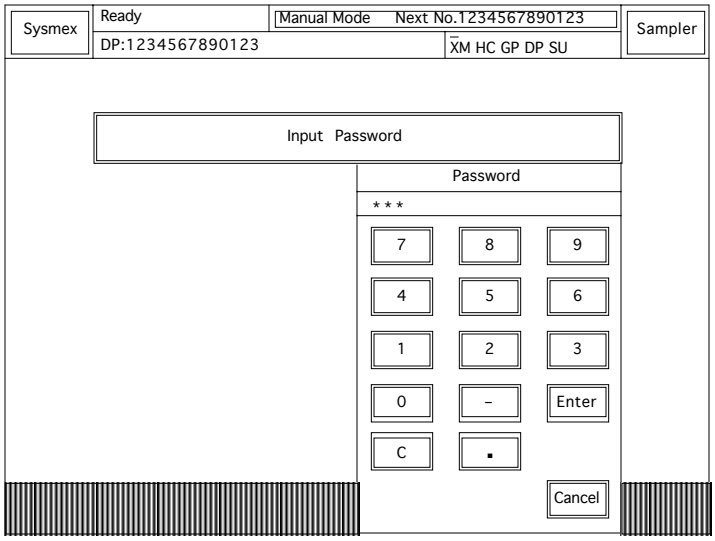

Figure 1-7: Password Entry Screen

The password is important for the management of the SF-3000, so be sure to memorize it and/or have aids to help you remember it. Should you forget it, consult your Sysmex service representative.

The password can consist of up to 12 digits. If you set the password to "0", no password check will be performed, and the programs will be executed without the need of password input.

For the procedures for setting and changing the password, refer to *Chapter 11, "System Setup"*.

11. EMERGENCY SHUTDOWN PROCEDURE

Should the analyzer need to be shut down in an emergency, such as a power failure in the laboratory, turn OFF the power switches of the following major components before the power is restored:

- Main Unit
- Pneumatic Unit

NOTE: If the Main Unit power is turned OFF during the system hard disk is being accessed ("HD" indicator appears in the System Status Area), the system memory check will be performed at next power ON. It will take approx. 15 minutes to complete the memory check.

NOTE: When the system is restarted and becomes ready status, perform the Waste Chambers and the WBC Detector cleaning sequences to remove the potentially remained sample and reagent in the hydraulic lines. Refer to *Chapter 5: Maintenance and Supplies* for the procedures.

12. ALARMS

In the SF-3000, 3 types of alarm sounds are used to alert the operator:

1. Key Entry
   A short beep (approx. 0.1 sec.) sounds every time a key is pressed on the LCD touch panel keypad.

2. Operation Error
   A long beep (approx. 1 sec.) sounds when a wrong key is pressed on the LCD touch panel keypad.

3. Analysis Error
   If any abnormality occurs in the Main Unit, a beep sounds and continues sounding until the [Alarm Reset] keypad is pressed. This keypad appears at the top left corner of the LCD instead of [Sysmex] keypad.

13. INSTALLATION REQUIREMENTS

13.1 Relocation Information

The SF-3000 and associated equipment should only be installed by your Sysmex service representative. Contact your Sysmex service representative if relocation of the system is required after it has been installed.

NOTE: Problems resulting from the relocation of the SF-3000 by anyone other than a Sysmex service representative are not covered by the Warranty.

The service agreement covers moving the SF-3000 after the warranty period has expired.

13.2 Electrical Requirements

The SF-3000 comes equipped with a three-prong or two-prong plug power cord. The type of cord and plug supplied depends on the source voltage for the system.

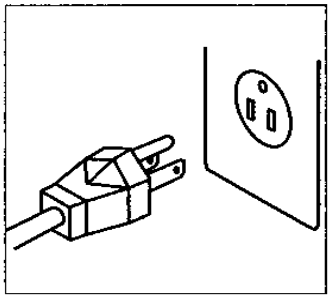

Figure 1-8: 117 VAC Plug

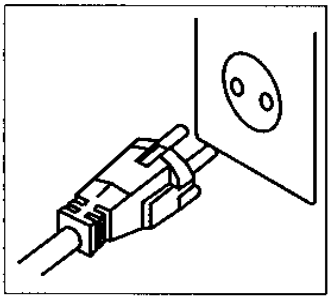

Figure 1-9: 220 VAC Plug

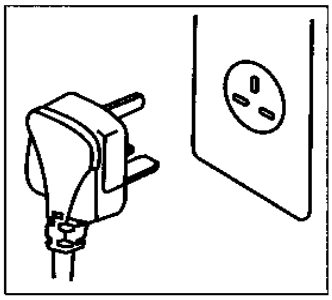

Figure 1-10: 240 VAC Plug

WARNING!: Proper use of the appropriate power cord assures adequate grounding for the system. Failure to properly ground the SF-3000 bypasses important safety features and may result in an electrical hazard.

The power source required for the SF-3000 system is: 117, 220 or 240 VAC ± 10%, 50/60 Hz.
The power consumption of the system, including the Pneumatic Unit and Sampler Unit, is 600 VA or less.

13.3 Space Requirements

It is important to install the instrument in a suitable location. A poor location can adversely affect its performance. Consider the following space requirements:

- Select a location near a power source and close to a suitable drain.
- Leave at least 0.5 m space on both sides, and at the rear and top of the system for easy maintenance and servicing. A minimum of 0.2 m must be maintained between the rear panel and the wall to allow for heat dissipation and tube clearance.
- Install the Pneumatic Unit, reagents and printers in suitable places that will make your work easy.

WARNING!: Install the Sampler Unit on a table or work bench. If the Sampler Unit is installed without supporting desktop under the unit, there is a possibility that the SF-3000 system could accidentally fall.

13.4 Installation Environment

The environmental requirements are listed below:

- Operate the SF-3000 within a temperature range of 15 - 30°C (optimum temperature 25°C) and relative humidity of 30 - 85%.
- To compensate for heat generated by the system, approximately 430 kcal/hour (1705 BTU/hour) is required in an air-conditioned environment. (This figure does not include additional cooling capacity required for the optional printers.)
- Avoid using the SF-3000 in areas of extreme temperature and direct sunlight.
- Place the SF-3000 in a well ventilated location.
- Avoid placing the SF-3000 near potentially interfering devices capable of emitting radio frequencies such as a radio or television receiver.

14. SYSTEM SPECIFICATIONS

Table 1-4: System Specifications

Parameters	WBC, NEUT%, LYMPH%, MONO%, EO%, BASO%, NEUT#, LYMPH#, MONO#, EO#, BASO#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, PDW, MPV, P-LCR
Reagents	Diluents : 1 (CELLPACK) WBC Reagents : 3 (STROMATOLYSER-FD (I), STROMATOLYSER-FD (II), STROMATOLYSER-FB) HGB Reagent : 1 (SULFOLYSER) Detergents : 1 (CELLCLEAN)
Aperture Diameter	RBC, PLT 75 µm
Throughput	Approximately 80 samples per hour (Approx. 85 seconds per sample)
Principles	WBC, LYMPH, MONO, NEUT, EO, BASO : Flow Cytometry with semiconductor laser beam RBC, PLT : DC Detection Method HGB : SLS Hemoglobin Method (at wavelength 555 nm) HCT : Cumulative Pulse Height Detection Method MCV : Calculated from RBC and HCT MCH : Calculated from RBC and HGB MCHC : Calculated from HCT and HGB
Sample Volume Required	Sampler Mode : Approx. 270 µL Closed Mode : Approx. 270 µL Manual Mode : Approx. 170 µL Capillary Mode : Over 40 µL
Data Storage Capacity	Cell size distribution data (with graphs) : for 1,000 samples Scattergrams : for 1,000 samples Order information : for 50 samples QC files : for 13 QC files
Quality Control	$\overline{X}$ Control (or L-J Control) : 180 points x 12 files, 28 parameters $\overline{X}$ M Control : 180 points x 1 file, 28 parameters

Table 1-4: System Specifications (Continued)

Precision for **Closed** and **Open** mode	Precision Characteristics are determined during instrument evaluation using one fresh normal **whole blood** sample analyzed ten times consecutively in Closed Sampling Auto Mode or Open Sampling Manual Mode. WBC CV 3.0% (when WBC ≥ 4.0 x 10^3/μL) NEUT% CV 8.0% (when NEUT% ≥ 30.0% and WBC ≥ 4.0 x 10^3/μL) LYMPH% CV 8.0% (when LYMPH% ≥ 15.0% and WBC ≥ 4.0 x 10^3/μL) MONO% CV 20.0% (when MONO% ≥ 5.0% and WBC ≥ 4.0 x 10^3/μL) EO% CV 25.0% or within ± 1.5 EO% (when WBC ≥ 4.0 x 10^3/μL) BASO% CV 40.0% or within ± 1.0 BASO% (when WBC ≥ 4.0 x 10^3/μL) NEUT# CV 8.0% (when NEUT# ≥ 1.20 x 10^3/μL) LYMPH# CV 8.0% (when LYMPH# ≥ 0.60 x 10^3/μL) MONO# CV 20.0% (when MONO# ≥ 0.20 x 10^3/μL) EO# CV 25.0% or within ± 0.12 x 10^3/μL BASO# CV 40.0% or within ± 0.06 x 10^3/μL RBC CV 1.5% (when RBC ≥ 4.00 x 10^6/μL) HGB CV 1.5% HCT CV 1.5% MCV CV 1.5% MCH CV 1.5% MCHC CV 2.0% PLT CV 5.0% (when PLT ≥ 100 x 10^3/μL) RDW-CV CV 3.0% RDW-SD CV 3.0% PDW CV 10.0% MPV CV 4.0% P-LCR CV 18.0%
Precision for **Capillary** mode	Precision Characteristics are determined during instrument evaluation using one fresh normal **capillary blood** sample analyzed ten times consecutively in Open Sampling Manual Mode. WBC CV 9.0% (when WBC ≥ 4.0 x 10^3/μL) RBC CV 4.5% (when RBC ≥ 4.00 x 10^6/μL) HGB CV 4.5% HCT CV 4.5% MCV CV 4.5% MCH CV 4.5% MCHC CV 6.0% PLT CV 15.0% (when PLT ≥ 100 x 10^3/μL)
Accuracy for **Closed** mode for **Open** mode	WBC within ± 3% or within 0.20 x 10^3/μL RBC within ± 2% or within 0.03 x 10^6/μL PLT within ± 5% or within 10 x 10^3/μL
Accuracy for **Capillary** mode	WBC within ± 10% RBC within ± 8% PLT within ± 12%

Table 1-4: System Specifications (Continued)

Differential Accuracy	The instrument differential is compared by using 100 or more fresh samples to the reference 400 cell manual differential (200 counts with 2 Lab. Techs.), as per NCCLS H-20A. MONO% is compared by using the monoclonal antibodies. Results are displayed as a range of values that are the mean differences between the methods, expressed to a 95% confidence interval. NEUT% Coefficient correlation $r \geq 0.90$ LYMPH% Coefficient correlation $r \geq 0.90$ MONO% Coefficient correlation $r \geq 0.75$ EO% Coefficient correlation $r \geq 0.80$ BASO% Coefficient correlation $r \geq 0.50$ Additionally, the mean difference from that obtained on the standard instrument should be the following: NEUT% within ± 3.0 NEUT% LYMPH% within ± 3.0 LYMPH% MONO% within ± 2.0 MONO% EO% within ± 1.0 EO% BASO% within ± 1.0 BASO%
Linearity for **Closed** and **Open** mode	WBC within ± 0.30 x 10^3/µL or within 3% for range 1.00-99.99 x 10^3/µL RBC within ± 0.03 x 10^6/µL or within 3% for range 0.30-9.99 x 10^6/µL HGB within ± 0.2 g/dL or within 2% for range 0.1-25.0 g/dL HCT within ± 1.0 HCT% or within 3% for range 10.0-60.0 HCT% PLT within ± 10 x 10^3/µL or within 5% for range 10-999 x 10^3/µL (Condition: RBC count is less than approx. 7.00 x 10^6/µL)
Linearity for **Capillary** mode	WBC within ± 0.50 x 10^3/µL or within 5% for range 1.00-99.99 x 10^3/µL RBC within ± 0.06 x 10^6/µL or within 6% for range 1.00-9.99 x 10^6/µL HGB within ± 0.7 g/dL or within 7% for range 2.0-25.0 g/dL HCT within ± 2.0 HCT% or within 6% for range 10.0-60.0 HCT% PLT within ± 20 x 10^3/µL or within 10% for range 10-999 x 10^3/µL (Condition: RBC count is less than approx. 7.00 x 10^6/µL)

NOTE: The Linearity range is different from the Display range. Consult the Linearity specification for the reportable range for each parameter. The Display range is given on the next page.

Table 1-4: System Specifications (Continued)

Carryover	WBC 3.0% or less RBC 1.5% or less HGB 1.5% or less HCT 1.5% or less PLT 1.5% or less
Maximum Allowable Difference between Manual Open Mode and Auto Mode	WBC Within ± 0.4 x $10^3/\mu L$ or ± 5% RBC Within ± 0.02 x $10^6/\mu L$ or ± 2% HGB Within ± 0.2 g/dL or ±2% HCT Within ± 0.3HCT% or ± 2% PLT Within ± 20 x $10^3/\mu L$ or ± 7% NEUT% Within ± 5.0% NEUT% LYMPH% Within ± 4.0% LYMPH% MONO% Within ± 3.0% MONO% EO% Within ± 2.0% EO% BASO% Within ± 1.0% BASO%
Display Range	WBC 0.00 - 999.99 x $10^3/\mu L$ RBC 0.00 - 99.99 x $10^6/\mu L$ HGB 0.0 - 30.0 g/dL HCT 0.0 - 100% PLT 0 - 9999 x $10^3/\mu L$
Peripheral Interface	Serial port for Host Computer Parallel port for Data Printer (DP-510, DP-490) Parallel port for Graphic Printer (DeskJet 560C/560J, LaserJet, Canon BJC 400J, LP-1500, LP-1600)
Dimensions H x W x D (mm), and Weight	Main Unit Approx. 580 x 451 x 600, 58 kg Pneumatic Unit Approx. 195 x 395 x 333, 15.5 kg Sampler Unit Approx. 580 x 280 x 302, 14.5 kg
Acceptable Barcodes	CODABAR, NW-7, CODE-11, CODE-39, CODE-128, Interleaved 2 of 5, JAN
Classification	Type of protection against electric shock Class I equipment Degree of protection against electric shock Type B applied part
Heat Compensation Required	Approx. 2047 BTU/h (516 kcal/h)

CHAPTER 2 SAMPLE PROCESSING

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1. INTRODUCTION

If your SF-3000 is equipped with the auto sampler unit (optional), analyses can be performed in four modes: manual open, capillary, auto (sampler), manual closed. If your SF-3000 is equipped with the manual CP unit (optional), analyses can be performed in three modes: manual open, capillary, manual CP mode.

This chapter explains the operation procedures for each mode.

1.1 Summary of Operation Mode

- **Manual Open Mode**
  In manual open mode, the cap of each sample tube is manually removed and the sample is aspirated via the whole blood aspiration pipette.

- **Capillary Mode**
  In capillary mode, an analysis is performed after diluting the sample to a 1:5 dilution. The method used to aspirate the sample is the same as that used in manual open mode.

- **Auto (Sampler) Mode**
  The closed sampler automatically mixes, aspirates, and analyzes samples without removing their caps. Up to 50 samples can be automatically analyzed at a time.

- **(Manual) Closed Mode**
  In manual closed mode, the sampler is used to aspirate the sample without opening the cap of the sample tube. Basically the same as auto mode; however, does not automatically mix or perform continuous analyses.

- **Manual CP Mode**
  In manual CP mode, the manual CP unit (option) is used to aspirate the sample, without opening the cap of the sample tube. Basically the same as manual closed mode; and does not automatically mix or perform continuous analyses.

1.2 Operational Procedures in Each Mode

Table 2-1: Operation Modes

<table>
<tr><td>Manual Open Mode</td><td>Capillary Mode</td><td>Auto Mode</td><td>Manual Closed Mode</td><td>Manual CP Mode</td></tr>
<tr><td colspan="5">Operator checks</td></tr>
<tr><td colspan="5">Turn ON power</td></tr>
<tr><td colspan="5">Self-check
Auto rinse</td></tr>
<tr><td colspan="5">Ready</td></tr>
<tr><td>Select manual mode</td><td>Select capillary mode</td><td>Press [Sampler]</td><td>Select closed mode</td><td>Select closed mode</td></tr>
<tr><td rowspan="2">Set Manual sample ID</td><td>Prepare capillary analysis sample (1:5 dilution)</td><td rowspan="2">Set sample ID (or read bar code label)

Set rack No.
Set tube No.</td><td rowspan="2">Set closed sample ID</td><td rowspan="2">Set closed sample ID</td></tr>
<tr><td>Set capillary sample ID</td></tr>
<tr><td colspan="2">Set sample at manual aspiration pipette</td><td colspan="2">Place sample in rack
Set rack on sampler</td><td>Place sample in Manual CP Unit</td></tr>
<tr><td colspan="2">Press the Start Switch</td><td>Press [Start]</td><td>Press the Start Switch</td><td>Press the Start Switch</td></tr>
<tr><td colspan="5">Analysis performed
Analysis complete</td></tr>
<tr><td colspan="5">Post-analysis check</td></tr>
<tr><td colspan="5">Perform shutdown</td></tr>
<tr><td colspan="5">Power OFF</td></tr>
</table>

Operations performed by the operator are indicated in **bold** print.

Ready: READY LED turns on and "Ready" message is displayed on the LCD screen. In this status, various operations can be executed, including analysis setting and data processing.

2. START-UP PROCEDURE

2.1 Operator Checks

1. Reagents

Make sure that there is a sufficient amount of reagent for the day's samples. If the amount is insufficient, prepare replacement reagent. If reagent runs out during an analysis, the system automatically stops and alerts the operator to replace the reagent. Analysis cannot be resumed until replacement is complete. Replace the reagent container by referring to the procedures in *Chapter 5: Maintenance and Supplies*.

The following shows the approximate number of cycles that can be analyzed per container of reagent.

Table 2-2: Cycles Analyzed per Reagent Container

Reagent		Number of Cycles Analyzed
CELLPACK	: Diluent	380 cycles per 20 L container
STROMATOLYSER-FB	: BASO Reagent	2,500 cycles per 5 L container
STROMATOLYSER-FD (I)	: 4Diff Reagent	2,500 cycles per 5 L container
STROMATOLYSER-FD (II)	: 4Diff Reagent	2,500 cycles per 500 mL bottle
SULFOLYSER	: HGB Reagent	1,000 cycles per 500 mL bottle

2. Printer Paper

Make sure that there is sufficient printer paper for the day's samples.

3. Equipment

Check the tubing and cables. Make sure that the tubing is not bent and the power cord is securely plugged into the power outlet.

4. Sampler

Make sure that there are no racks on the analysis line. Remove any rack from the line. Make sure that the left and right rack pools and analysis line are clear.

5. Waste Fluid

Discharge any waste fluid that has been collected in the pneumatic unit drain trap and waste container (if applicable).

2.2 Turning On the Power

Turn ON the power switches in the following order: 1) Printers, 2) Pneumatic Unit and 3) Main Unit. The message "Please Wait" will be displayed on the LCD after approximately 10 seconds. The pressure and vacuum will reach their preset values approximately 30 seconds after the power is turned ON.

CAUTION: • If the Data Printer (DP-510) is connected, turn ON the power switch of the Main Unit first, then the DP-510.

NOTE: • The power of the Pneumatic Unit is controlled by the Main Unit; thus, you can normally leave the Pneumatic Unit power switch ON.

2.3 Self-Checks

The instrument performs a self-check operation automatically after the power is turned ON. The following checks are performed in order: microprocessor check, program loading, temperature/pneumatic check, mechanical parts check, and background check. If any failure occurs during the self-check process, see *Chapter 8: Troubleshooting*.

1. Microprocessor Check and Program Loading

When the power is turned on, the message "System test in progress. Wait for a moment..." will be displayed and the microprocessor performs system and memory tests automatically. If any error occurs during the self-check, an error message appears on the screen. Jot down the message and turn the power OFF and ON again. If the same error message appears, contact a Sysmex service representative.
When the microprocessor check is completed, the system program will be automatically loaded from the hard disk. The message "Now Loading System. Wait for a moment..." is displayed during the program loading.

NOTE: If the Main Unit is powered OFF during the system hard disk is being accessed ("HD" indicator appears in the System Status Area), the system memory check will be performed after program loading when the system is started next time. The message "Verifying stored data. Please wait..." will appear. It will take approx. 15 minutes to complete the memory check.

2. Temperature/Pressure Check

After the program loading is completed, the messages "Running" and "Start-up" will be displayed on the LCD. The pressure and vacuum are monitored until they reach the preset range. At the same time, the program advances to the temperature check and the temperature of the WBC analysis system is checked. Wait until pressure, vacuum and temperature have reached the allowable range and the message disappears.
If the message is still displayed 30 minutes after the power has been turned ON, the instrument is probably malfunctioning. In this case, turn OFF the power and contact a Sysmex service representative.

3. Mechanical Parts Check

After the temperature and pressure/vacuum checks are completed, the following functions will be checked.

- Sampling valve operation
- Whole blood aspiration motor and sheath motor operation
- Whole blood manual aspiration pipette rinsing

4. Background Check

After the mechanical parts check is completed, the message "Auto Rinse" appears. After an auto rinse cycle is completed, the background values are checked. If the background values are less than or equal to those shown in the table below, the background check is complete.

Table 2-3: Acceptable Background Limits

Parameters	Acceptable Limits
WBC/BASO Channel	0.1 [x $10^3/\mu L$]
DIFF Channel	0.1 [x $10^3/\mu L$]
RBC	0.02 [x $10^6/\mu L$]
HGB	0.1 [g/dL]
PLT	10 [x $10^3/\mu L$]

If any of the limits are exceeded, the background check is repeated again. A maximum of two additional rinse cycles will be performed. If any parameter exceeds the acceptable limit in both the second and third checks, the background check stops, the message "Background Error" appears with the corresponding parameter name, and the alarm sounds.

NOTE: The parameter which the background data exceeded the acceptable limit is shown in the Status Display. Press [Status] keypad in the root menu.

In the case of a background error, analysis can be performed; however, the measured values may be somewhat high. Press [More] key to display the [Auto Rinse] key. Press the [Auto Rinse] key to perform a background check again. If the parameters are still not within the acceptable range, see *Chapter 8, Troubleshooting*.

2.4 Pressure Gauge Check

The pressure and vacuum gauges should reach their specified levels approximately 30 seconds after the power is turned ON. Confirm that the gauges indicate the values shown below. If they do not, adjust to the acceptable range.

Table 2-4:
Required Pressure and Vacuum

Pressure	1.8 kg/cm^2 or higher
Vacuum	400 mmHg or higher

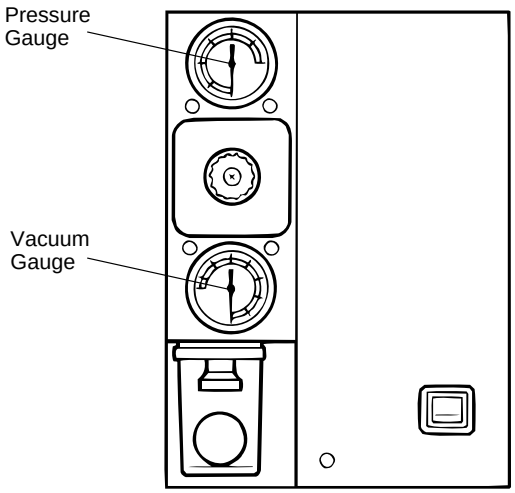


Figure 2-1: Pressure and Vacuum Gauges (Pneumatic Unit - Front)

2.5 Auto Output Settings Check

If Auto Output to the peripheral printer(s) and/or a host computer is desired, before starting analysis, make sure that the instrument is set to automatically transmit/print. See *Chapter 11: System Setup.*

3. QUALITY CONTROL ANALYSIS

Control samples (SF CHECK) are analyzed and the data is stored in the $\overline{X}$ or L-J quality control file. Follow the manufacturer's instructions for handling control material. Quality control analysis data is stored in specifically designated QC files. For details see *Chapter 6: Quality Control*.

NOTE: Using the $\overline{X}$ Control method, the control sample is analyzed twice in succession and the average data point is used. The L-J Control method, on the other hand, uses the result from one analysis as one control data point.

3.1 QC Analysis: Manual Mode

Follow the procedure below to perform QC analysis in Manual mode. The instrument will be in Manual mode after the power is turned ON.

(1) Make sure that the READY LED is lit in green.

(2) Press the Next No. keypad in the top line of the LCD. The Sample No. Setting screen shown below will appear.

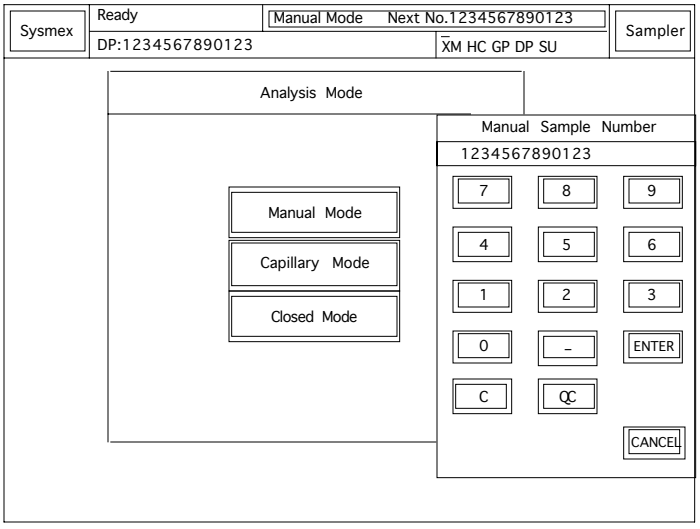


Figure 2-2: Sample No. Setting Screen

(3) The selected analysis mode is backlit in light-blue. Press [Manual Mode] to select Manual mode, if needed.

(4) Press [QC] key, then specify the file No. using the numerical keypads.
For example to specify the QC file No. 1, press [QC] and [1] keypads.

NOTE:
- When SF CHECK is used, files 1 through 12 can be designated.
- The QC file No. is displayed in two digits. For instance when pressing [QC] and [1], the file No. will be displayed as "QC01".
- Use "QC" - "Target/Limit" - "Lot Info." program to verify that the control lot number, expiration date, analysis mode (Manual) and necessary information are set for the specified QC file. Refer to *Chapter 6, Section 6.6: Lot Information* for the procedure.

(5) Press the [ENTER] key. The QC file No. is specified and the QC Data Display for the specified file will appear as shown below.

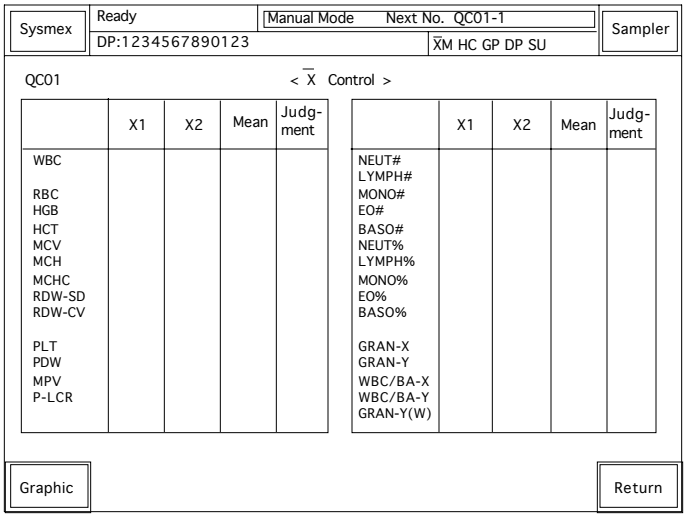


Figure 2-3: QC Data Display Screen ($\overline{X}$ Control)

(6) To analyze the control material in the Manual mode, see *Section 4.1: Manual Mode* in this chapter.

(7) After the analysis is completed, the results are displayed.
When the [Return] key is pressed, the program ends and the control data is automatically accepted and plotted.

NOTE: Press the [Graphic] key on the QC Data Display screen to display the graphic display.

- When $\overline{X}$ Control program is used:

  The results of the first analysis are displayed in the "X1" column when completed as shown in Figure 2-4. The sample No. on the graphic screen is shown, for example, as "QC01-1".

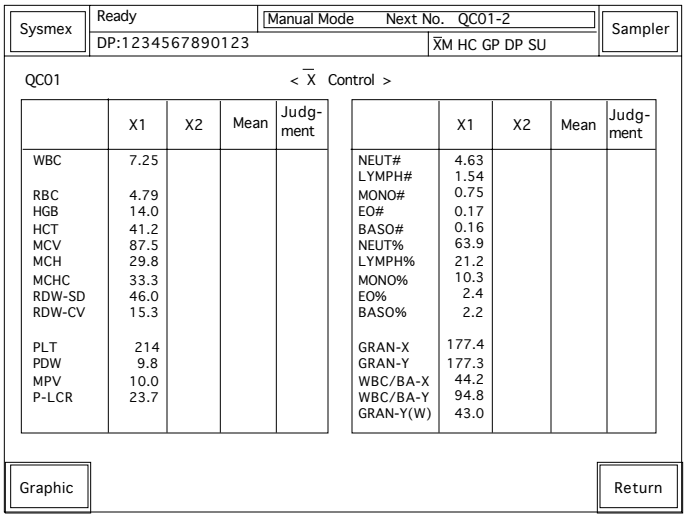
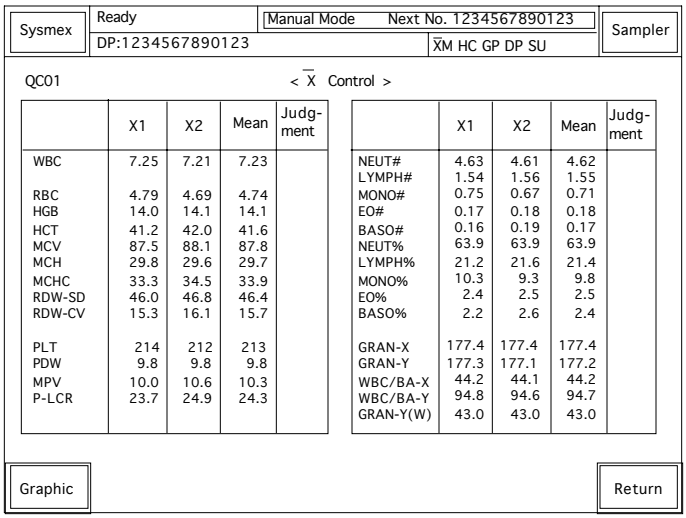


Figure 2-4: "X1" Data Display (Manual Mode)

NOTE: If the results of the first analysis are not acceptable, re-enter the QC file No. as "QC01-1" and re-analyze the control. The data in the "X1" column will be replaced with the newly obtained results, and the new data will be handled as the $\overline{X}$ Control first data.

When the second analysis is completed, the results are displayed in "X2" column. Then, the mean (average) values of the first and the second analysis results will be displayed in the "Mean" column. Refer to Figure 2-5a. The sample No. on the graphic screen is indicated as "QC01" (see Figure 2-5b).

NOTE: Two analysis results obtained consecutively without any abnormality are used for the $\overline{X}$ Control.



	X1	X2	Mean	Judg-ment
WBC	7.25	7.21	7.23	
RBC	4.79	4.69	4.74	
HGB	14.0	14.1	14.1	
HCT	41.2	42.0	41.6	
MCV	87.5	88.1	87.8	
MCH	29.8	29.6	29.7	
MCHC	33.3	34.5	33.9	
RDW-SD	46.0	46.8	46.4	
RDW-CV	15.3	16.1	15.7	
PLT	214	212	213	
PDW	9.8	9.8	9.8	
MPV	10.0	10.6	10.3	
P-LCR	23.7	24.9	24.3	

	X1	X2	Mean	Judg-ment
NEUT#	4.63	4.61	4.62	
LYMPH#	1.54	1.56	1.55	
MONO#	0.75	0.67	0.71	
EO#	0.17	0.18	0.18	
BASO#	0.16	0.19	0.17	
NEUT%	63.9	63.9	63.9	
LYMPH%	21.2	21.6	21.4	
MONO%	10.3	9.3	9.8	
EO%	2.4	2.5	2.5	
BASO%	2.2	2.6	2.4	
GRAN-X	177.4	177.4	177.4	
GRAN-Y	177.3	177.1	177.2	
WBC/BA-X	44.2	44.1	44.2	
WBC/BA-Y	94.8	94.6	94.7	
GRAN-Y(W)	43.0	43.0	43.0	

Figure 2-5a: QC Data Display Screen (Manual Mode)

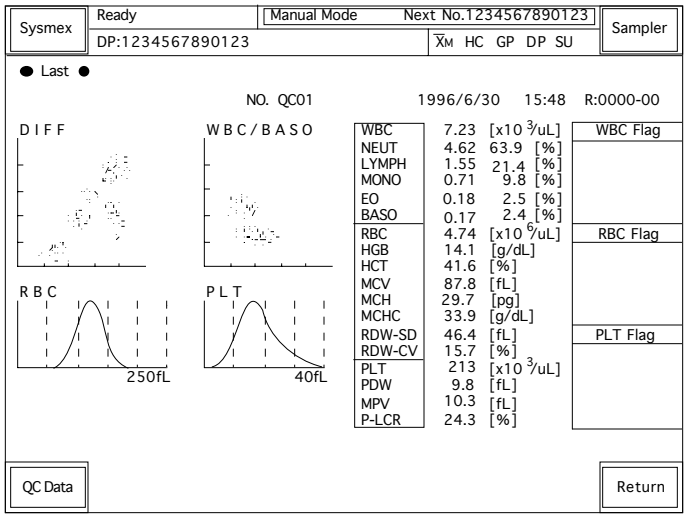


Figure 2-5b: Control Data Graphic Display (Manual Mode)

- When L-J Control program is used:
  The QC analysis results are displayed as shown in Figure 2-6. The sample No. on the graphic display is indicated as "QC01".

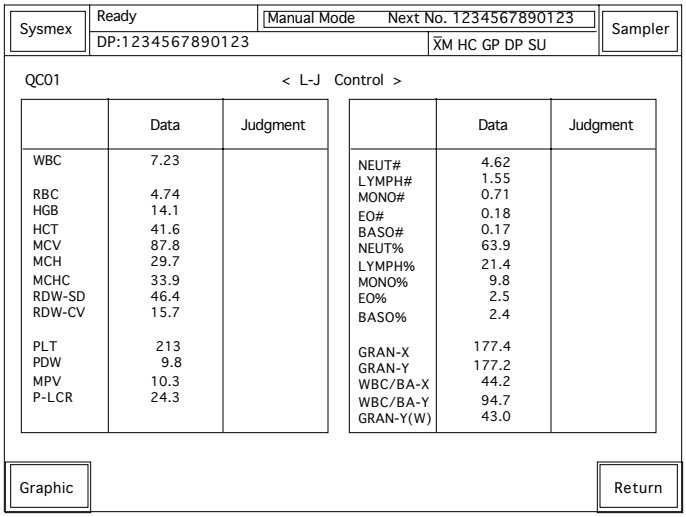


Figure 2-6: QC Data Display Screen (L-J Control)

NOTE:	If the displayed results are not acceptable, re-enter the QC File No. as "QC01" and re-analyze the control. The data in the "Data" column will be replaced with the newly obtained results, and the new data will be handled as the L-J Control data.

If the error message < $\overline{X}$ Limit Error> or <L-J Limit Error> appears in the system status area (upper portion of the LCD), the analyzed data has exceeded the control limit.

The "+" or "-" sign in yellow backlight will be displayed in the "Judgment" column and the "Check Control Chart" message window appears. On the graphic display, the "+" or "-" sign in yellow backlight will also be added to the parameter which is outside the control limits. Check the control chart and review the control data. Reanalyze the sample, if needed. Refer to *Chapter 6: Quality Control*.

When the message "Reanalyze Control" appears, the analyzed data is more than 3 times the limit and will not be recorded in memory. The "+" or "-" sign in red backlight will be displayed in the "Judgment" column. On the graphic display, the "+" or "-" sign in red backlight will also be added to the parameter which is outside the control limits. Reanalyze the sample.

If an analysis error occurs during QC analysis, the error message <QC Analysis Error> will be displayed. The results are not plotted as a control data point. Reanalyze the sample.

3.2 QC Analysis: Auto Mode

Execute L-J can be performed in auto (sampler) mode if SF CHECK is used. Follow the procedure below to execute quality control analyses in auto mode.

NOTE: $\overline{X}$ Control cannot be performed in Auto mode.

(1) Check the volume of control material.
Required sample volume: 1.0 mL or more
Aspirated sample volume: 270 µL

NOTE: When SF CHECK is used, files 1 through 12 can be designated in advance.

(2) Use the Lot Information of Target/Limit submenu to verify the control lot information for the control file to be used. See *Chapter 6: Quality Control* for the procedures.

(3) To analyze the control material in the auto mode, see *Section 4.3: Auto Mode* in this chapter. After analysis is completed, the results are recorded in the file designated by the bar code.

NOTE: The QC Data Display screen as shown in Figure 2-6 on the previous page will not be displayed for the QC analysis in Auto mode.

When the "Check Control Chart" message window appears, the analyzed data has exceeded the control limit. Check the control chart and review the control data. See *Chapter 6: Quality Control* for QC chart review information.
When the message "Reanalyze Control" appears, the analyzed data is more than 3 times the limit and will not be recorded in memory. Reanalyze the sample.

NOTE: The expiration date of SF CHECK is monitored if the expiration date information is entered in the control file. "Control Expired" will be reported when SF CHECK is analyzed and the lot has already been expired. The analyzed data will not be plotted on the QC chart.

Refer to *Chapter 6, Section 9: Sampler QC Analysis* for further information.

3.3 QC Analysis: Manual Closed Mode

QC analyses can be performed in Manual Closed mode if the sampler unit is installed and SF CHECK is used. Follow the procedure below to execute quality control analyses in Closed mode.

(1) Make sure that the READY LED is lit.

(2) Press the Next No. keypad in the top line of the LCD. The Sample No. Setting screen will appear.

(3) The selected analysis mode is backlit in light-blue. Press [Closed Mode] to select Closed mode, if needed.

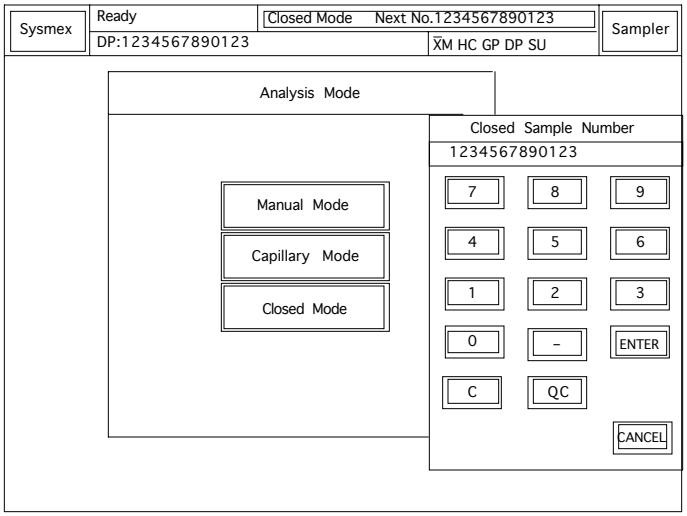


Figure 2-7: Sample No. Setting Screen (Closed Mode)

(4) Press [QC] key, then specify the file No. using the numerical keypads. For example to specify the QC file No. 3, press the [QC] and the [3] keypad.

NOTE:
- When SF CHECK is used, files 1 through 12 can be designated.
- The QC file No. is displayed in two digits. For instance when pressing [QC] and [3], the file No. will be displayed as "QC03".
- Use "QC" - "Target/Limit" - "Lot Info." program to verify that the control lot number, expiration date, analysis mode (Closed) and necessary information are set for the specified QC file. Refer to *Chapter 6, Section 6.6: Lot Information* for the procedure.

(5) Press the [ENTER] key. The QC file No. is specified and the QC Data Display will appear as shown in Figure 2-8.

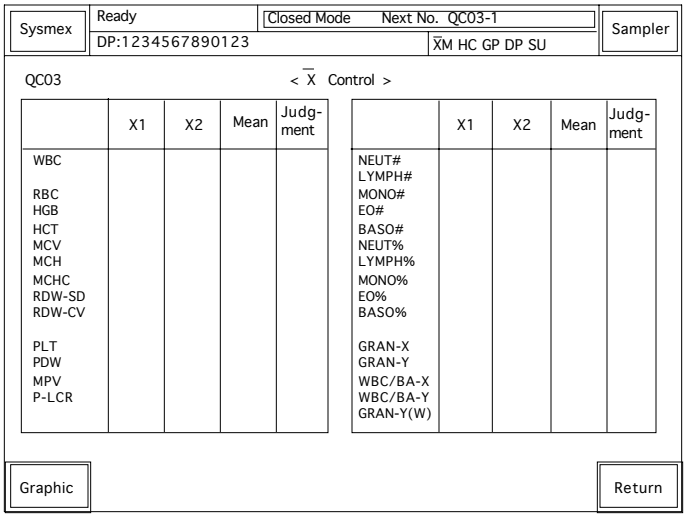


Figure 2-8: QC Data Display Screen ($\overline{X}$ Control)

(6) To analyze the control material in the Manual Closed mode, see *Section 4.4: Manual Closed Mode* in this chapter.

(7) After the analysis is completed, the results are displayed.
When the [Return] key is pressed, the program ends and the control data is automatically accepted and plotted.

> **NOTE:** Press the [Graphic] key on the QC Data Display screen to display the graphic display.

- When $\overline{X}$ Control program is used:

  The results of the first analysis are displayed in the "X1" column when completed. The sample No. on the graphic screen is shown, for example, as "QC03-1".

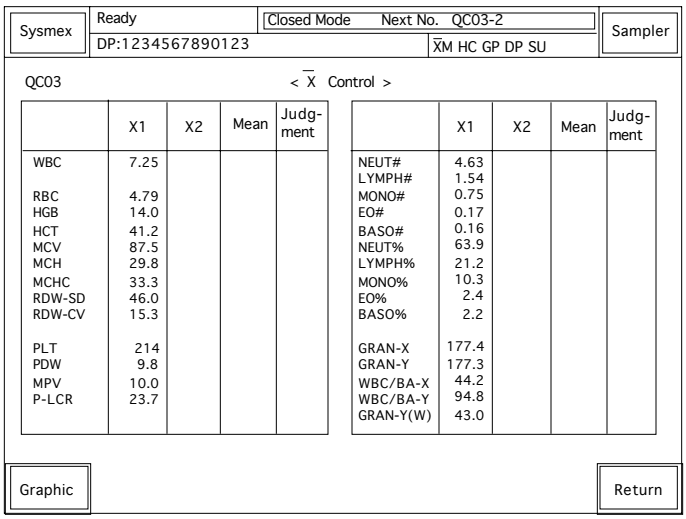
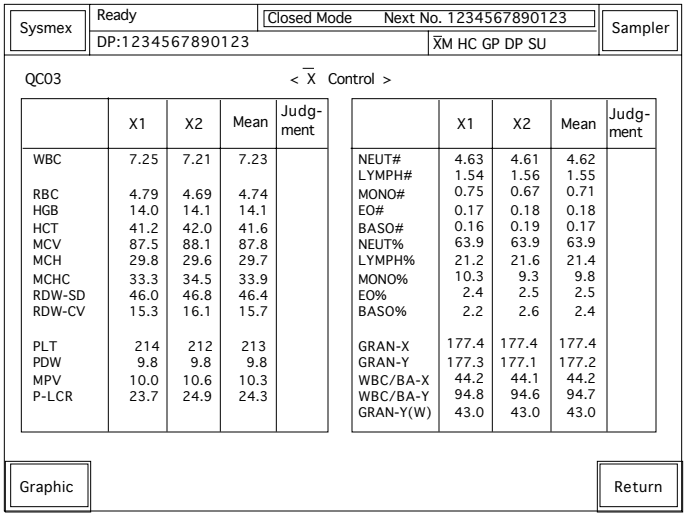


Figure 2-9a: "X1" Data Display (Closed Mode)

NOTE: If the results of the first analysis are not acceptable, re-enter the QC file No. as "QC03-1" and re-analyze the control. The data in the "X1" column will be replaced with the newly obtained results, and the new data will be handled as the $\overline{X}$ Control first data.

When the second analysis is completed, the results are displayed in "X2" column. Then, the mean (average) values of the first and the second analysis results will be displayed in the "Mean" column. Refer to Figure 2-9b. The sample No. on the graphic screen is indicated as "QC03" (see Figure 2-9c).

NOTE: Two analysis results obtained consecutively without any abnormality are used for the $\overline{X}$ Control.



	X1	X2	Mean	Judg-ment
WBC	7.25	7.21	7.23	
RBC	4.79	4.69	4.74	
HGB	14.0	14.1	14.1	
HCT	41.2	42.0	41.6	
MCV	87.5	88.1	87.8	
MCH	29.8	29.6	29.7	
MCHC	33.3	34.5	33.9	
RDW-SD	46.0	46.8	46.4	
RDW-CV	15.3	16.1	15.7	
PLT	214	212	213	
PDW	9.8	9.8	9.8	
MPV	10.0	10.6	10.3	
P-LCR	23.7	24.9	24.3	

	X1	X2	Mean	Judg-ment
NEUT#	4.63	4.61	4.62	
LYMPH#	1.54	1.56	1.55	
MONO#	0.75	0.67	0.71	
EO#	0.17	0.18	0.18	
BASO#	0.16	0.19	0.17	
NEUT%	63.9	63.9	63.9	
LYMPH%	21.2	21.6	21.4	
MONO%	10.3	9.3	9.8	
EO%	2.4	2.5	2.5	
BASO%	2.2	2.6	2.4	
GRAN-X	177.4	177.4	177.4	
GRAN-Y	177.3	177.1	177.2	
WBC/BA-X	44.2	44.1	44.2	
WBC/BA-Y	94.8	94.6	94.7	
GRAN-Y(W)	43.0	43.0	43.0	

Figure 2-9b: QC Data Display Screen (Closed Mode)

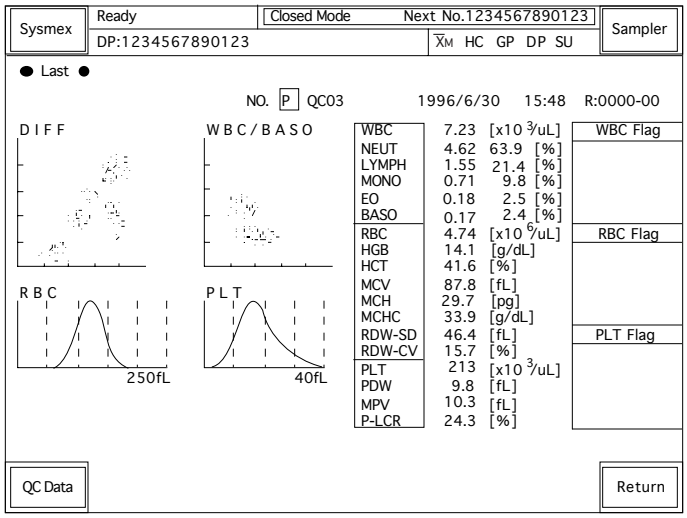


Figure 2-9c: Control Data Graphic Display (Closed Mode)

- When L-J Control program is used:
  The QC analysis results are displayed as shown in Figure 2-10. The sample No. on the graphic display is indicated as "QC03".

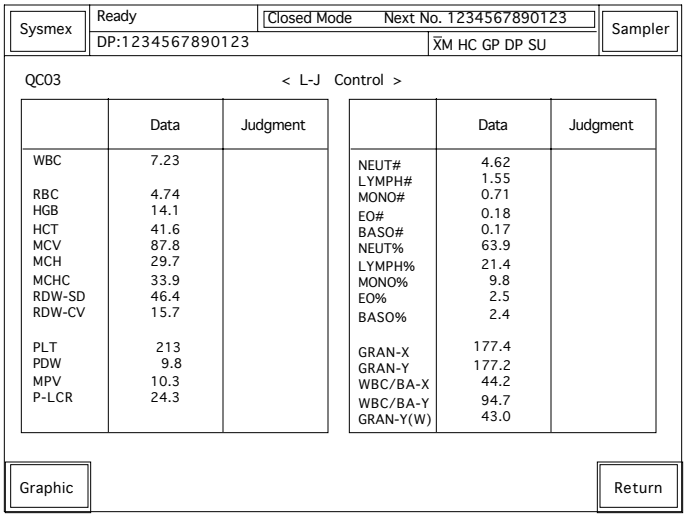


Figure 2-10: QC Data Display Screen (L-J Control)

NOTE: If the displayed results are not acceptable, re-enter the QC File No. as "QC03" and re-analyze the control. The data in the "Data" column will be replaced with the newly obtained results, and the new data will be handled as the L-J Control data.

If the error message < $\overline{X}$ Limit Error> or <L-J Limit Error> appears in the system status area (upper portion of the LCD), the analyzed data has exceeded the control limit.

The "+" or "-" sign in yellow backlight will be displayed in the "Judgment" column and the "Check Control Chart" message window appears. On the graphic display, the "+" or "-" sign in yellow backlight will also be added to the parameter which is outside the control limits. Check the control chart and review the control data. Reanalyze the sample, if needed. Refer to *Chapter 6: Quality Control*.

When the message "Reanalyze Control" appears, the analyzed data is more than 3 times the limit and will not be recorded in memory. The "+" or "-" sign in red backlight will be displayed in the "Judgment" column. On the graphic display, the "+" or "-" sign in red backlight will also be added to the parameter which is outside the control limits. Reanalyze the sample.

If an analysis error occurs during QC analysis, the error message <QC Analysis Error> will be displayed. The results are not plotted as a control data point. Reanalyze the sample.

3.4 QC Analysis: Manual CP Mode

QC analyses can be performed in Manual Closed mode if the Manual CP Unit is installed and SF CHECK is used. Follow the procedure below to execute quality control analyses in Manual CP mode.

The procedures to select the Closed mode, to select QC file and the results displays are the same as those in the Manual Closed mode. Refer to the previous *Section 3.3: QC Analysis: Manual Closed Mode* for the detailed procedures.
To analyze the control material in the Manual CP mode, see *Section 4.5: Manual CP Mode* in this chapter.

4. ANALYSIS MODE PROCEDURES

4.1 Manual Mode

Manual mode operation can be performed when the system is in the READY mode. Operation in this mode requires the operator to mix, uncap the sample, and manually introduce the specimen to the analyzer.

Analysis of the sample is performed in the following steps:

1. Collect and prepare sample
2. Select Manual mode
3. Input sample ID number
4. Analyze sample
5. Display analysis results
6. Output analysis results
7. Perform post-analysis procedures

1. Collect and Prepare Sample

Draw the specified amount of blood (corresponding to the amount of EDTA anticoagulant).

CAUTION:
- Some anticoagulants will alter test results due to their effects on hemolysis and blood platelet agglutination. Therefore, use K_2 EDTA, K_3 EDTA, or Na_2 EDTA as the anticoagulant.
- Samples must be warmed to room temperature for approximately 30 minutes before analysis.

The height of the blood sample tube should be 75 mm or shorter. Sample volumes are shown below.

Aspirated sample volume: Approx. 170 µL

2. Select Manual Mode

If "Manual Mode" does not appear on the LCD display, follow the procedure below to select Manual mode.

(1) Press the Next No. keypad in the top line of the LCD. The Sample No. Setting screen shown below will appear.

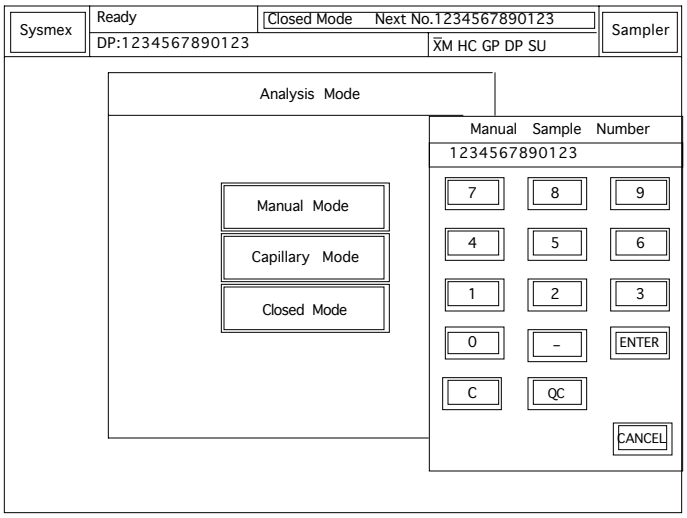


Figure 2-11: Sample No. Setting Screen (Manual Mode)

(2) The selected analysis mode is backlit in light-blue. Press [Manual Mode] to select Manual mode.

3. Input Sample ID Number

Using the Sample No. Setting Screen, input the next sample ID number to be analyzed as described below, if needed.

(1) The next sample number to the previously analyzed sample in Manual mode appears above the numerical keys. Clear the number by pressing [C] key and input the sample ID number with the numerical keys, if needed.

NOTE: When the next sample No. is not set, or after the power ON, the next sample No. is automatically set to No. 1, increasing by 1 for each succeeding sample (e.g., 1, 2, 3, ...).

(2) Press [ENTER]. The next sample No. is set and the Sample No. Setting screen will disappear. The input sample No. will be displayed in the Next No. column in the top line of the LCD.

CAUTION: Do not use zero as the sample ID number. If the ID number is set to zero, the analysis results will neither be stored nor output. If the sample ID number is set to zero, continuous short beeps will sound during sample aspiration to alert the operator.

NOTE:
- The sample ID can include numbers (0-9) and hyphens up to a maximum of 13 characters.
- Hyphens cannot be placed at the beginning or end of the sample ID number, nor can two hyphens be placed consecutively.
- A number will not be carried beyond a hyphen. For example, the number following 2-999 will be 2-000; 1-99-000 will follow 1-99-999.
- The number following 9999999999999 will be 1.

4. Analyze Sample

(1) Mix the whole blood sample thoroughly by inverting the tube.

(2) Remove the cap carefully so as not to splatter blood.

(3) Set the sample tube into the manual aspiration pipette as shown in the figure; then press the Start Switch. Do not remove the sample tube while the READY LED is blinking; sample is being aspirated.

(4) After the READY LED turns off (and beep sounds three times), remove the sample tube.

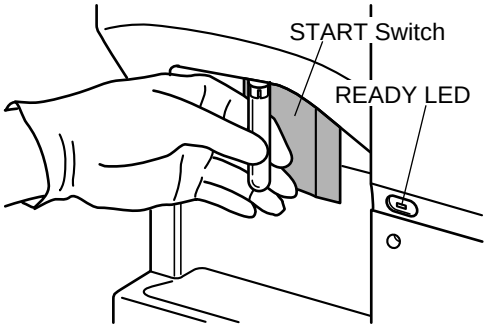


Figure 2-12: Introduce Sample

CAUTION:
- You must remove the sample tube within 5 seconds after the READY LED turns off, because the manual rinse cup moves down.
- To remove the sample, pull straight down to prevent bending the manual aspiration pipette.
- The manual aspiration pipette is automatically rinsed, and does not need to be wiped manually.

(5) When the READY LED turns on again, "Sample Asp Ready" message is displayed. Prepare the next sample and repeat steps (1)-(4).

NOTE: If sample ID numbers are not set, they are automatically assigned sequentially.

After the sample is aspirated, the analysis begins. You can check the status of each stage of analysis using the Analysis Process screen. To see this screen, press [Status] key in the root menu. Switch to "P2. Analysis Process" using the [→] and [←] keys.

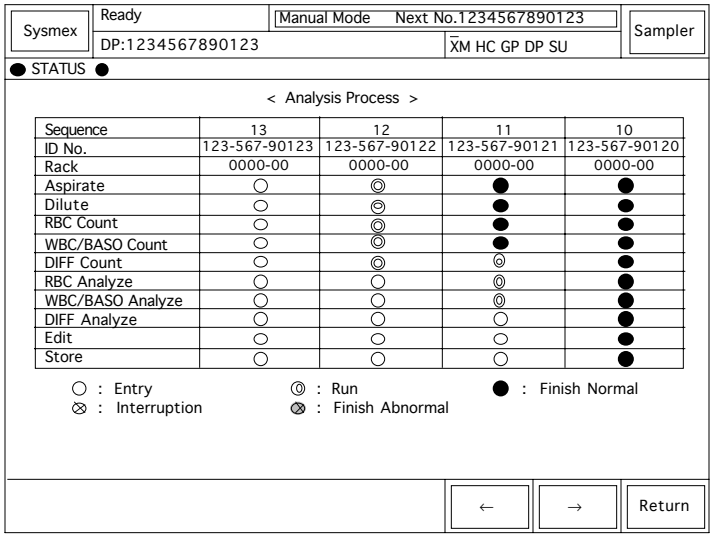


Figure 2-13: Analysis Process Screen (Manual Mode)

5. Display Analysis Results

After analysis is completed (approximately 85 seconds after the sample is aspirated), the results are displayed on the screen.

CAUTION: If all the following conditions are met, the sample is assumed blank and the analysis result will neither be stored nor judged against any flagging criteria.

WBC	<	1.00	x $10^3/\mu L$
RBC	<	0.30	x $10^6/\mu L$
HGB	<	1.0	g/dL
PLT	<	20	x $10^3/\mu L$

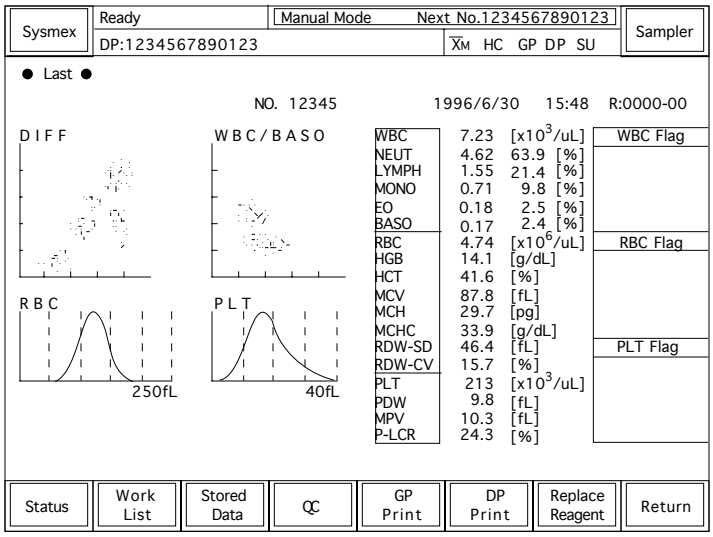


Figure 2-14: Analysis Results Screen (Manual Mode)

6. Output Analysis Results

If automatic output has been set, the analysis results will be sent to the Graphic Printer, Data Printer, and/or Host Computer.
If automatic output has not been set, the operator must select the data and destination for the output. See *Chapter 4: Result Interpretation/Reports*.

7. Perform Post-Analysis Procedures

Residual blood and reagent can cause detector aperture to clog and protein to build up in aspiration lines. If the instrument is not to be used for a while, press the [Auto Rinse] key in the root menu to execute a background check.

NOTE: If the [Auto Rinse] key is not displayed on the LCD, press [More] key to change the root menu display.

4.2 Capillary Mode

Capillary mode operation can be performed when the system is in the READY mode. Operation in this mode requires the operator to manually dilute, mix, uncap, and introduce the diluted specimen to the analyzer.

Analysis of the sample is performed in the following steps:

1. Collect and prepare sample
2. Select capillary mode
3. Input sample ID number
4. Prepare 1:5 dilution of sample
5. Analyze sample
6. Display analysis results
7. Output analysis results
8. Perform post-analysis procedures

1. Collect and Prepare Sample

Using CELLPACK dispensed ahead of time, dilute the sample to a 1:5 ratio.

CAUTION: With blood samples taken from the earlobe or fingertip, generally as the blood count increases, reproducibility decreases. If possible, analyze the diluted sample twice, and compare the results. When a heparin-coated capillary tube or something similar is used, depending on the anticoagulant, hemolysis or platelet agglutination occurs; this can alter the analysis results. Use K_2 EDTA, K_3 EDTA, or Na_2 EDTA as the anticoagulant.

The height of the blood sample tube should be 75 mm or shorter. Sample volumes are shown below.

Required sample volume:	40 µL or more
Diluted sample volume aspirated:	Approx. 170 µL

2. Select Capillary Mode

If "Capillary Mode" does not appear on the LCD display, follow the procedure below to select capillary mode.

(1) Press the Next No. keypad in the top line of the LCD. The Sample No. Setting screen will appear.

(2) The selected analysis mode is backlit in light-blue. Press [Capillary Mode] to select capillary mode.

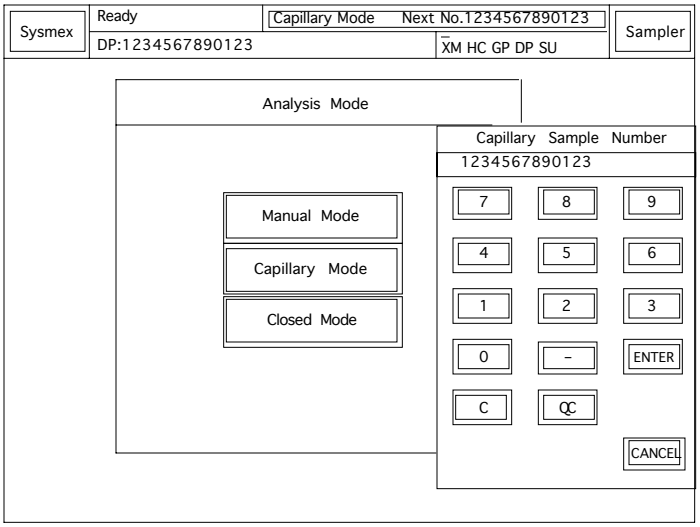


Figure 2-15: Sample No. Setting Screen (Capillary Mode)

NOTE: The Next No. keypad is indicated in yellow back light .

3. Input Sample ID Number

Using the Sample No. Setting Screen, input the next sample ID number to be analyzed as described below, if needed.

(1) The next sample number to the previously analyzed sample in Capillary mode appears above the numerical keys. Clear the number by pressing [C] key and input the sample ID number with the numerical keys, if needed.

NOTE: When the next sample No. is not set, or after the power ON, the next sample No. is automatically set to No. 1, increasing by 1 for each succeeding sample (e.g., 1, 2, 3, ...).

(2) Press [ENTER]. The next sample No. is set and the Sample No. Setting screen will disappear. The input sample No. will be displayed in the Next No. column in the top line of the LCD.

CAUTION: Do not use zero as the sample ID number. If the ID number is set to zero, the analysis results will neither be stored nor output. If the sample ID number is set to zero, continuous short beeps will sound during sample aspiration to alert the operator.

NOTE:
- The sample ID can include numbers (0-9) and hyphens up to a maximum of 13 characters.
- Hyphens cannot be placed at the beginning or end of the sample ID number, nor can two hyphens be placed consecutively.
- A number will not be carried beyond a hyphen. For example, the number following 2-999 will be 2-000; 1-99-000 will follow 1-99-999.
- The number following 9999999999999 will be 1.

4. Prepare 1:5 Dilution of Sample

Prepare a 1:5 dilution using the following materials:

- Diluent (CELLPACK)
- Microtube (MT-40, etc.)
- 40 µL pipette (40 µL SMI micropettor, mode 1058-D40)
- 160 µL pipette (50 µL-250 µL SMI micropettor, model 1200-J, etc.)
- Diluent dispensing container (beaker, etc.)
- Diluent dispensing equipment (pipettor, etc.)

(1) Rinse a beaker with CELLPACK, to eliminate dust, etc.

(2) Carefully dispense CELLPACK into the beaker with a pipettor.

(3) Carefully transfer 160 µL of CELLPACK from the beaker with a micro pipettor to the capillary analysis container (e.g. Micro Centrifuge Tube).

(4) Pipette 40 µL of patient blood to the capillary analysis container containing the 160 µL of CELLPACK.

(5) Cap and mix well.

NOTE: Prepare and analyze the 1:5 sample dilution as soon after collection as possible to minimize platelet agglutination. Also, if diluent is dispensed ahead of time, measurement errors are generated because of evaporation and contaminants; therefore, prepare new diluted sample each time an analysis is performed.

5. Analyze Sample

(1) Mix the capillary sample thoroughly.

(2) Set the sample tube into the manual aspiration pipette as shown in the figure; then press the Start Switch. Do not remove the sample tube while the READY LED is blinking; sample is being aspirated.

(3) After the READY LED turns off (and beep sounds three times), remove the sample tube.

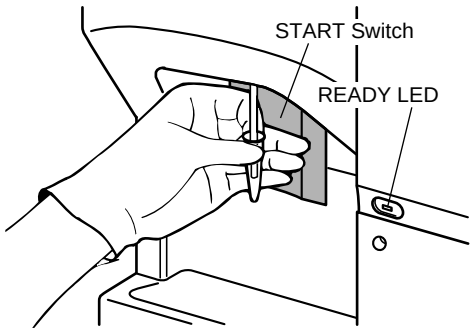


Figure 2-16: Introduce Sample

CAUTION:
- You must remove the sample tube within 5 seconds after the READY LED turns off, because the manual rinse cup moves down.
- To remove the sample, pull straight down to prevent bending the manual aspiration pipette.
- The manual aspiration pipette is automatically rinsed, and does not need to be wiped manually.

(4) When the READY LED turns on again, "Sample Asp Ready" is displayed. Prepare the next sample and repeat steps (1)-(3) above.

NOTE: If sample ID numbers are not set, they are automatically assigned sequentially.

After the sample is aspirated, the analysis begins. You can check the status of each stage of analysis using the Analysis Process screen. To see this screen, press [Status] key in the root menu. Switch to "P2. Analysis Process" using the [→] and [←] keys.

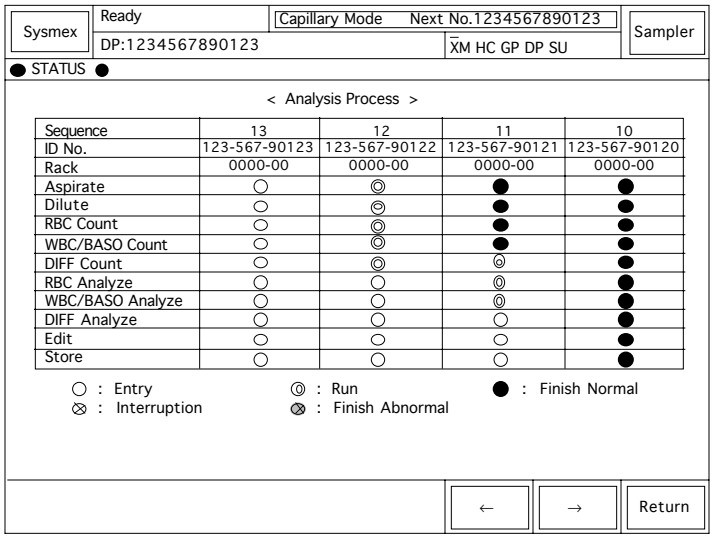
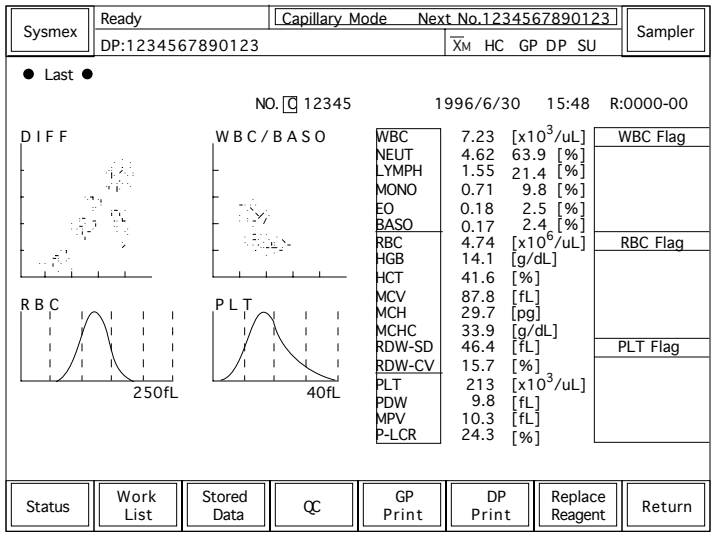


Figure 2-17: Analysis Process Screen (Capillary Mode)

6. Display Analysis Results

After analysis is completed (approximately 85 seconds after the sample is aspirated), the results are displayed on the screen.

NOTE: "C" in green backlight is added to the left of Sample ID No.



In capillary mode, the following flags are available with the 8 CBC parameters (WBC, RBC, HGB, HCT, MCV, MCH, MCHC and PLT):

(1) Error function indication
(2) Error limit marks "+" and "–"
(3) Linearity limit mark "*"
(4) POSITIVE flag (no NEGATIVE flag is displayed.)
(5) The following IP messages:

WBC:	Leukocytopenia	Leukocytosis
RBC:	Microcytosis	Macrocytosis
	Hypochromia	Anemia
	Erythrocytosis	
PLT:	Thrombocytopenia	Thrombocytosis

Analyzed results other than the 8 CBC parameters are not reported in the capillary mode.

CAUTION: If all the following conditions are met, the sample is assumed blank and the analysis result will be neither stored nor judged against any flagging criteria.

WBC	<	1.00	x 10^3/µL
RBC	<	0.30	x 10^6/µL
HGB	<	1.0	g/dL
PLT	<	20	x 10^3/µL

7. Output Analysis Results

If automatic output has been set, the analysis results will be sent to the Graphic Printer, Data Printer, and/or Host Computer.
If automatic output has not been set, the operator must select the data and destination for the output. See *Chapter 4: Result Interpretation/Reports*.

8. Perform Post-Analysis Procedures

Residual blood and reagent can cause detector aperture to clog and protein to build up in aspiration lines. If the instrument is not to be used for a while, press the [Auto Rinse] key in the root menu to execute an auto rinse and a background check.

NOTE: If the [Auto Rinse] key is not displayed on the LCD, press [More] key to change the root menu display.

If no further capillary specimens require processing, return the system to Manual mode as follows:

(1) Press the Next No. keypad in the top line of the LCD. The Sample No. Setting screen will appear.

(2) Press the [Manual Mode] key to select Manual mode, and press the [Enter] key.

4.3 Auto Mode

Auto (sampler) mode operation can be performed when the system is in the READY mode. This mode permits automatic mixing, aspiration, and analysis of samples.

Analysis of the sample is performed in the following steps:

1. Collect and prepare sample
2. Input sample ID number
3. Analyze sample
4. Display analysis results
5. Output analysis results
6. Perform post-analysis procedures

1. Collect and Prepare Sample

(1) Collect sample.
Draw the specified amount of blood (corresponding to the amount of EDTA anticoagulant).

CAUTION:
- Some anticoagulants will alter test results due to their effects on hemolysis and blood platelet agglutination. Therefore, use K_2 EDTA, K_3 EDTA, or Na_2 EDTA as the anticoagulant.
- Samples must be warmed to room temperature for approximately 30 minutes before analysis.

Sample volumes required for analyses are shown below.

Table 2-5: Volume of Sample Required

	Diameter of Sample Tube	
	12 mm	15 mm
Required sample volume	1.0 to 5.0 mL	1.0 to 7.0 mL
Aspirated sample volume	Approx. 270 µL	

Use the type of blood collection tube shown below for auto mode analyses.

Diameter	a:	12 - 15 mm
Length	b:	75 mm
Overall length	c:	82 mm or less

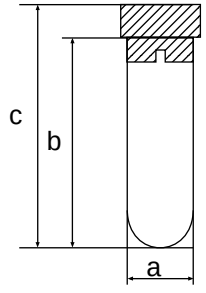


Figure 2-19: Tube Dimensions

CAUTION:
- If VENOJECT® II collection tubes are to be used, some engineering change is required. Contact a Sysmex service representative.
- Recapped VENOJECT® II collection tube cannot be used. Such a collection tube maybe dropped while mixing or piercing due to a removed cap.

Use blood sample tubes with a height of 75 mm (overall height including rubber cap is 82 or less) and a diameter of 12, 13, 14 or 15 mm. If tubes have diameters of less than 14 mm, attach adapters to the rack.

Table 2-6: Adapter Requirement

Tube Outer Diameter	Adapter
12 mm	No. 58
13 mm	No. 56
14 mm	None
15 mm	None

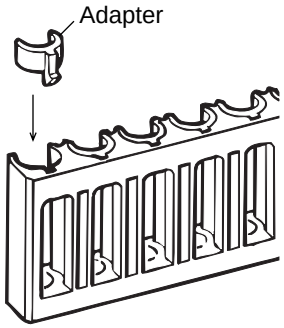


Figure 2-20: Adapter

(2) Make sure that the label is in the proper location so that the bar code can be correctly read. Affix the bar code label as shown in the figures below (tubes and/or racks).
Also, when setting a sample tube in the rack, make sure that all of the bar codes can be seen through the rack slits.

Sample Tube
(Sample ID number bar code label)

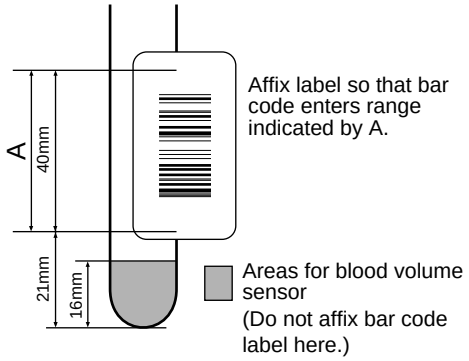


Figure 2-21: Affix Sample Tube Bar Code Label

Rack
(Rack number bar code label)

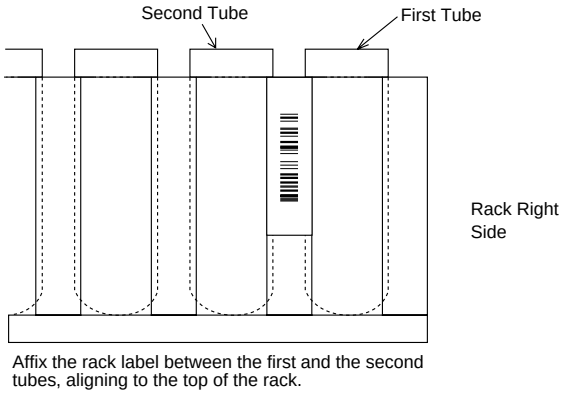
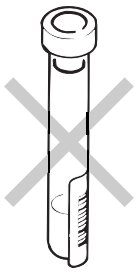

Second Tube
First Tube
Rack Right Side
Affix the rack label between the first and the second tubes, aligning to the top of the rack.

Figure 2-22: Affix Rack Bar code Label

CAUTION:
- If the bar code is affixed in the area of blood volume sensor, the volume of sample cannot be accurately monitored.
- To prevent instrument damage and ensure that the tube can be properly mixed and sampled, make sure that the bar code label does not extend beyond the bottom of the sample tube.



2. Input Sample ID Number (if bar code not used)

If an ID bar code reader is not used, the sample ID number must be input manually before analysis is performed.

(1) Make sure that the instrument is in Ready status. The READY LED should be lit and the message "Ready" should appear on the LCD.

(2) Press the [Sampler] keypad in the upper right corner of the LCD. The Sampler Start Check window will appear.

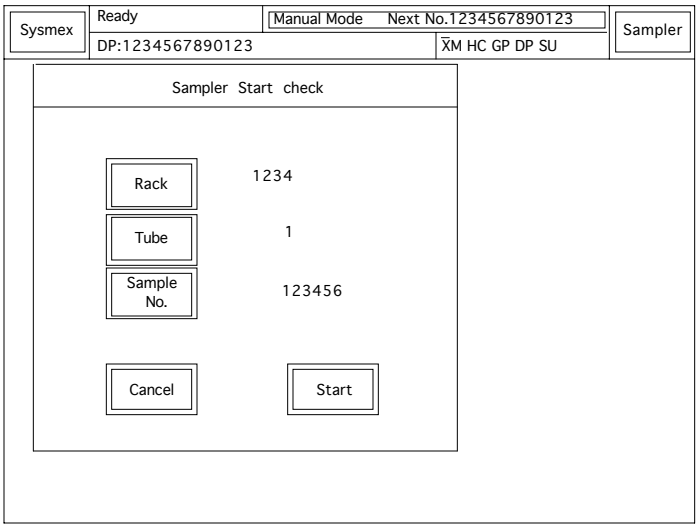


Figure 2-23: Sampler Start Check Window

(3) Press the [Sample No.] key. The numerical keys will appear as shown in figure below.

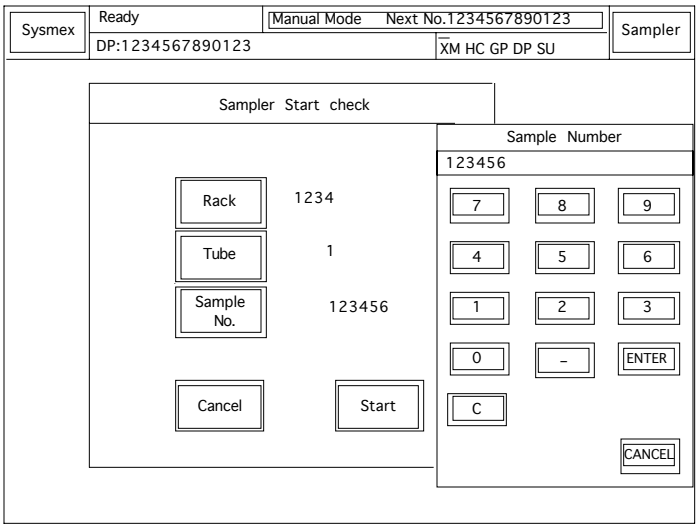


Figure 2-24: Auto Mode Sample No. Input Screen

(4) The next sample number to the previously analyzed sample in Auto mode appears above the numerical keys. Clear the number by pressing [C] key and input a new sample ID number with the numerical keys, if needed.

NOTE:
- After the power ON, the next sample No. is automatically set to No. 1, increasing by 1 for each succeeding sample (e.g., 1, 2, 3, ...).
- When less than 10 samples are set in a rack, the Sample Nos. will be automatically assigned for the vacant tube position(s). Therefore, for example, when the next Sample No. is set to "1" and the Tube No. is set to "5", the analysis for the rack ends with Sample No. 6.

(5) Press [ENTER]. The numerical keypad will disappear. Verify that the input sample number is displayed to the right of [Sample No.] key.

NOTE:
- The sample ID cannot be set to zero.
- The initial value is 1, with the number increasing by 1 for each succeeding sample (e.g., 1, 2, 3, ...).
- The sample ID can include numbers (0-9) and hyphens up to a maximum of 13 characters.
- Hyphens cannot be placed at the beginning or end of the sample ID number, nor can two hyphens be placed consecutively.
- A number will not be carried beyond a hyphen. For example, the number following 2-999 will be 2-000; 1-99-000 will follow 1-99-999.
- The number following 9999999999999 will be 1.

(6) Press the [Rack] key. The numerical keys will appear for rack number entry.

(7) Input the rack number with the numerical keys. The rack number can consist of up to 4 digits.

(8) Press [ENTER]. The screen returns to Sampler Start Check screen with the entered rack number displayed.

NOTE: Rack numbers (Rack No.) increase by 1 as each new rack arrives at the analysis line.

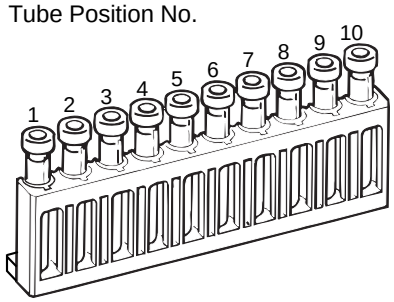
(9) Press the [Tube] key. The numerical keys will appear for tube position entry.

(10) Input the tube position number to be analyzed first within the rack with the numerical keys. The tube position number can consist of up to 2 digits.

NOTE: The Auto mode analysis will start from the sample at the set Tube Position No. Therefore, when the next Tube Position is set to "3", the samples in Tube Position 1 and 2 will be ignored and will not be analyzed.

(11) Press [ENTER]. The screen returns to Sampler Start Check screen with the entered tube position number displayed.

NOTE:
- Because the initial value is 1, this setting is not needed when beginning the analysis with the sample on the far left of the rack.
- The blood sample tube position number (Tube Pos. No.) shows the location of each tube in the rack.



3. Analyze Sample

(1) Put the sample tubes in the rack, and set the rack in the right rack pool of the sampler. Each rack holds up to 10 sample tubes.

(2) Press the [Start] key in the Sampler Start Check window. The instrument performs mixing, aspirating, and analyzing until all of the samples in a rack in the right rack pool have been analyzed.

(3) When all of the racks have moved to the left rack pool of the sampler, the READY LED turns on.

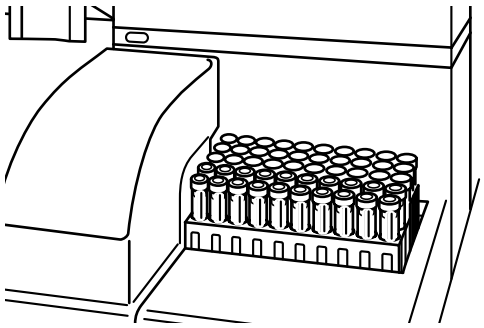


Figure 2-25: Load Racks on the Sampler

CAUTION: Do not remove the cover from the Piercer Unit during sampler operation.

NOTE:
- The [Sampler] key alternates with [Sampler Stop] key. During sampler analysis, [Sampler Stop] key appears.
- If you press the [Sampler Stop] key during sampler analysis, the sampler stops and stat (manual) analysis can be performed.

After the sample is aspirated, the analysis begins. You can check the status of each stage of analysis using the Analysis Process screen. To see this screen, press [Status] key in the root menu. Switch to "P2. Analysis Process" using the [→] and [←] keys.

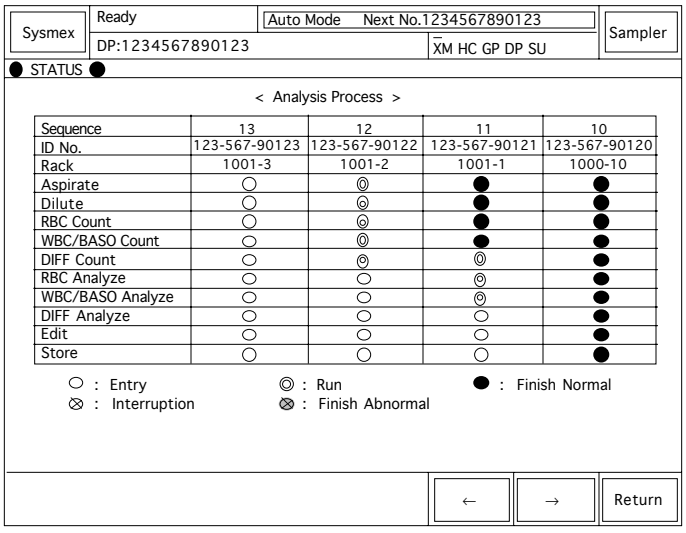


Figure 2-26: Analysis Process Screen (Auto Mode)

- **Stat Analysis in Auto Mode**

(1) Press the [Sampler Stop] key to interrupt the sampler operation. When the messages "Ready" and "STAT" appear on the LCD, manual analysis can be performed.

(2) Press the Next No. keypad in the top line of the LCD. The Sample No. Setting screen will appear.

(3) The selected analysis mode is backlit in light-blue. Press [Manual Mode] to select Manual mode, if needed.

(4) Input the sample ID number for the Stat analysis with the numerical keys, and press [ENTER]. The sample No. is set and the Sample No. Setting screen will disappear.

(5) Process the sample as if it were a routine manual mode sample. While the sample is being processed, the message "Running" will appear on the LCD.

(6) After the Stat analysis is completed, the message "Ready" will appear on the LCD again; press the [Sampler] key.

(7) The Sampler Start Check window will appear. Press [Start] key to resume the sampler operation.

4. Display Analysis Results

After analysis is completed (approximately 85 seconds after the sample is aspirated), the results are displayed on the screen.

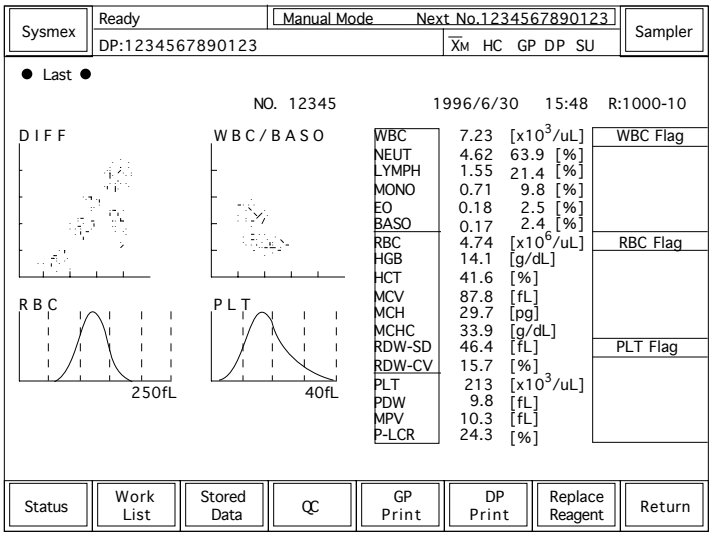


Figure 2-27: Analysis Results Screen (Auto Mode)

CAUTION: If all the following conditions are met, the sample is assumed blank and the analysis result will be neither stored nor judged against any flagging criteria.

WBC	<	1.00	x 10^3/µL
RBC	<	0.30	x 10^6/µL
HGB	<	1.0	g/dL
PLT	<	20	x 10^3µL

5. Output Analysis Results

If automatic output has been set, the analysis results will be sent to the Graphic Printer, Data Printer, and/or Host Computer.
If automatic output has not been set, the operator must select the data and destination for the output. See *Chapter 4: Result Interpretation/Reports*.

6. Perform Post-Analysis Procedures

Residual blood and reagent can cause detector aperture to clog and protein to build up in aspiration lines. If the instrument is not to be used for a while, press the [Auto Rinse] key in the root menu to execute a background check.

NOTE: If the [Auto Rinse] key is not displayed on the LCD, press [More] key to change the root menu display.

4.4 Manual Closed Mode

Analyses in Manual Closed mode can be performed when the system is in the READY mode. In this mode, samples are manually mixed, set one at a time into a rack, and analyzed.

Analysis of the sample is performed in the following steps:

1. Collect and prepare sample
2. Select closed mode
3. Input sample ID number
4. Analyze sample
5. Display analysis results
6. Output analysis results
7. Perform post-analysis procedures

1. Collect and Prepare Sample

Draw the specified amount of blood (corresponding to the amount of EDTA anticoagulant).

CAUTION:
- Some anticoagulants will alter test results due to their effects on hemolysis and blood platelet agglutination. Therefore, use K_2 EDTA, K_3 EDTA, or Na_2 EDTA as the anticoagulant.
- Samples must be warmed to room temperature for approximately 30 minutes before analysis.

The height of the blood sample tube should be 75 mm or shorter. Sample volumes are shown below.

Required sample volume:	1.0 mL or more
Aspirated sample volume:	Approx. 270 µL

Use the type of blood collection tube shown below for Manual Closed analysis.

Diameter	a:	12 - 15 mm
Length	b:	75 mm
Overall length	c:	82 mm or less

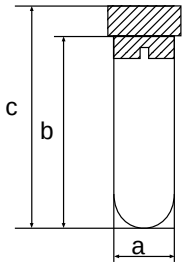


Figure 2-28: Tube Dimensions

CAUTION:
- If VENOJECT® II collection tubes are to be used, contact a Sysmex service representative for assistance.
- Recapped VENOJECT® II collection tube cannot be used. While inverting or piercing such a collection tube, the cap may be removed.

2. Select Closed Mode

If "Closed Mode" does not appear on the LCD display, follow the procedure below to select closed mode.

(1) Press the Next No. keypad in the top line of the LCD. The Sample No. Setting screen will appear.

(2) The selected analysis mode is backlit in light-blue. Press [Closed Mode] to select Closed mode.
The messages "Not Ready" and "Mode Change" appear in the top line of the LCD. After the system condition becomes ready for analysis, "Ready" and "Closed Mode" will be displayed.

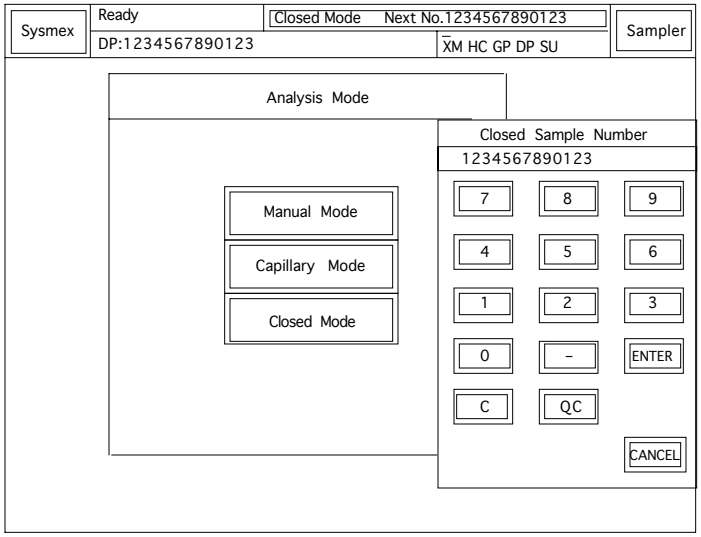


Figure 2-29: Sample No. Setting Screen (Closed Mode)

3. Input Sample ID Number

Using the Sample No. Setting Screen, input the next sample ID number to be analyzed as described below, if needed.

(1) The next sample number to the previously analyzed sample in Closed mode appears above the numerical keys. Clear the number by pressing [C] key and input the sample ID number with the numerical keys, if needed.

NOTE: When the next sample No. is not set, or after the power ON, the next sample No. is automatically set to No. 1, increasing by 1 for each succeeding sample (e.g., 1, 2, 3, ...).

(2) Press [ENTER]. The next sample No. is set and the Sample No. Setting screen will disappear. The input sample No. will be displayed in the Next No. column in the top line of the LCD.

CAUTION: Do not use zero as the sample ID number. If the ID number is set to zero, the analysis results will be neither stored nor output. If the sample ID number is set to zero, continuous short beeps will sound during sample aspiration to alert the operator.

NOTE:
- The sample ID can include numbers (0-9) and hyphens up to a maximum of 13 characters.
- Hyphens cannot be placed at the beginning or end of the sample ID number, nor can two hyphens be placed consecutively.
- A number will not be carried beyond a hyphen. For example, the number following 2-999 will be 2-000; 1-99-000 will follow 1-99-999.
- The number following 9999999999999 will be 1.

4. Analyze Sample

(1) Mix the whole blood sample thoroughly by inverting the tube; then insert it into the far left position of a rack (tube position No. 1).

(2) Set the rack in the sampler's right rack pool.

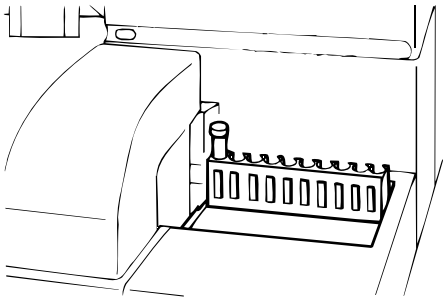


Figure 2-30: Load Rack on Sampler

(3) Press the Start Switch to start the analysis.

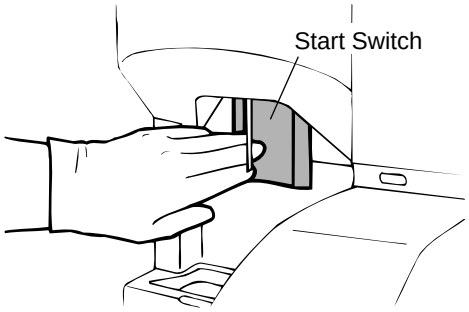


Figure 2-31: Press the Start Switch

After the rack is automatically moved laterally three times to the piercer hand, sample aspiration begins. You can check the status of each stage of analysis using the Analysis Process screen. To see this screen, press [Status] key in the root menu. Switch to "P2. Analysis Process" using the [→] and [←] keys.

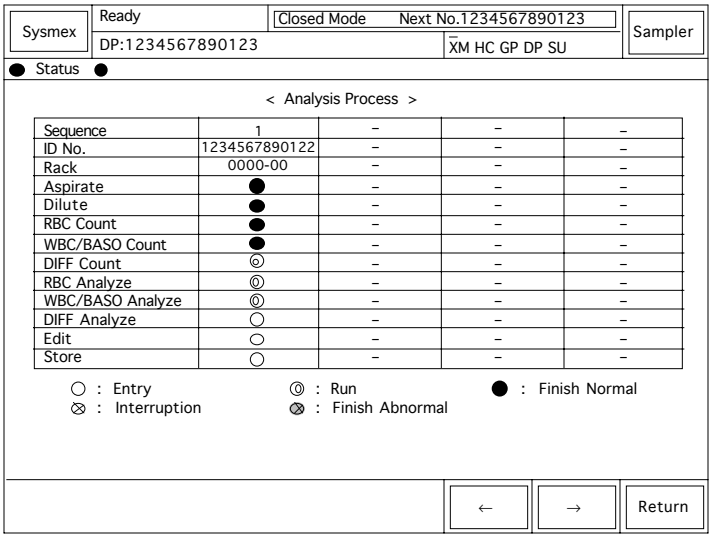


Figure 2-32: Analysis Process Screen (Closed Mode)

6. Display Analysis Results

After analysis is complete (approximately 85 seconds after the sample is aspirated), the results are displayed on the screen.

NOTE: "P" in green back light is added to the left of Sample ID No.

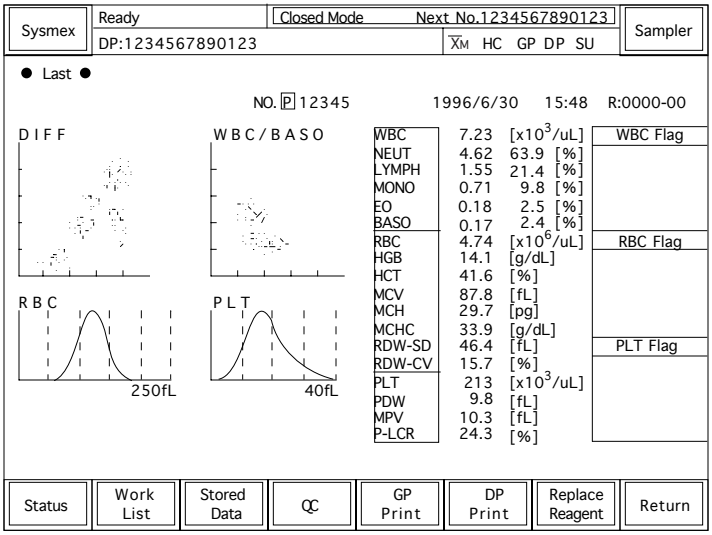


Figure 2-33: Analysis Results Screen (Closed Mode)

CAUTION: If all the following conditions are met, the sample is assumed blank and the analysis result will be neither stored nor judged against any flagging criteria.

WBC	<	1.00	x $10^3/\mu L$
RBC	<	0.30	x $10^6/\mu L$
HGB	<	1.0	g/dL
PLT	<	20	x $10^3/\mu L$

7. Output Analysis Results

If automatic output has been set, the analysis results will be sent to the Graphic Printer, Data Printer, and/or Host Computer.
If automatic output has not been set, the operator must select the data and destination for the output. See *Chapter 4: Result Interpretation/Reports.*

8. Perform Post-Analysis Procedures

Residual blood and reagent can cause detector aperture to clog and protein to build up in aspiration lines. If the instrument is not to be used for a while, press the [Auto Rinse] key in the root menu to execute an auto rinse and a background check.

NOTE:	If the [Auto Rinse] key is not displayed on the LCD, press [More] key to change the root menu display.

If no further specimens require processing, return the system to Manual mode as follows:

(1) Press the Next No. keypad in the top line of the LCD. The Sample No. Setting screen will appear.

(2) Press the [Manual Mode] key to select manual analysis mode, and press the [ENTER] key.

4.5 Manual CP Mode

Analyses in Manual CP mode can be performed when the system is in the READY mode. In this mode, samples are manually mixed, set one at a time in the Manual CP unit, and analyzed.

Analysis of the sample is performed in the following steps:

1. Collect and prepare sample
2. Select closed mode
3. Input sample ID number
4. Analyze sample
5. Display analysis results
6. Output analysis results
7. Perform post-analysis procedures

1. Collect and Prepare Sample

Draw the specified amount of blood (corresponding to the amount of EDTA anticoagulant).

CAUTION:
- Some anticoagulants will alter test results due to their effects on hemolysis and blood platelet agglutination. Therefore, use K_2 EDTA, K_3 EDTA, or Na_2 EDTA as the anticoagulant.
- Samples must be warmed to room temperature for approximately 30 minutes before analysis.

The height of the blood sample tube should be 75 mm or shorter. Sample volumes are shown below.

Required sample volume:	1.0 mL or more
Aspirated sample volume:	Approx. 270 µL

Use the type of blood collection tube shown below for Manual CP mode analyses.

Diameter	a:	12 - 15 mm
Length	b:	75 mm
Overall length	c:	82 mm or less

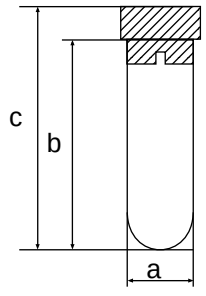


Figure 2-34: Tube Dimensions

CAUTION:
- If VENOJECT® II collection tubes are to be used, some engineering change is required. Contact a Sysmex service representative.
- Recapped VENOJECT® II collection tube cannot be used. While inverting or piercing such a collection tube, the cap may be removed.

2. Select Closed Mode

If "Closed Mode" does not appear on the LCD display, follow the procedure below to select Manual mode.

(1) Press the Next No. keypad in the top line of the LCD. The Sample No. Setting screen will appear.

(2) The selected analysis mode is backlit in light-blue. Press [Closed Mode] to select Manual CP mode.
The messages "Not Ready" and "Mode Change" appear in the top line of the LCD. After the system condition becomes ready for analysis, "Ready" and "Closed Mode" will be displayed.

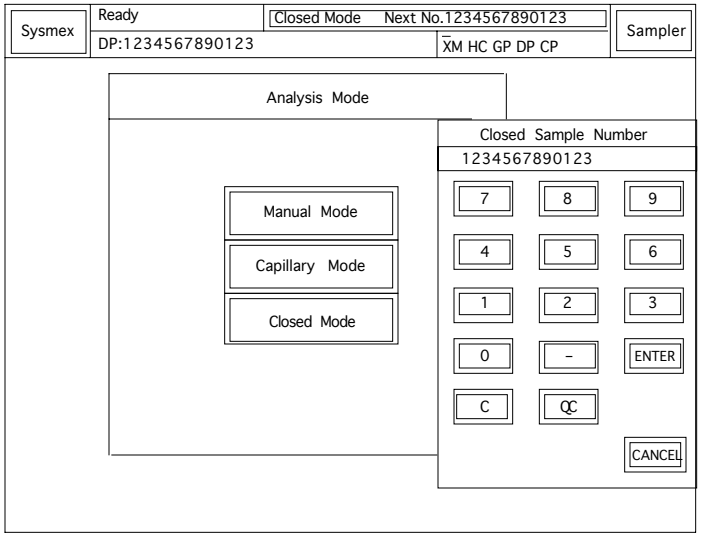


Figure 2-35: Sample No. Setting Screen (Manual CP/Closed Mode)

3. Input Sample ID Number

Using the Sample No. Setting Screen, input the next sample ID number to be analyzed as described below, if needed.

(1) The next sample number to the previously analyzed sample in Manual CP mode appears above the numerical keys. Clear the number by pressing [C] key and input the sample ID number with the numerical keys, if needed.

NOTE: When the next sample No. is not set, or after the power ON, the next sample No. is automatically set to No. 1, increasing by 1 for each succeeding sample (e.g., 1, 2, 3, ...).

(2) Press [ENTER]. The next sample No. is set and the Sample No. Setting screen will disappear. The input sample No. will be displayed in the Next No. column in the top line of the LCD.

CAUTION: Do not use zero as the sample ID number. If the ID number is set to zero, the analysis results will be neither stored nor output. If the sample ID number is set to zero, continuous short beeps will sound during sample aspiration to alert the operator.

NOTE:
- The sample ID can include numbers (0-9) and hyphens up to a maximum of 13 characters.
- Hyphens cannot be placed at the beginning or end of the sample ID number, nor can two hyphens be placed consecutively.
- A number will not be carried beyond a hyphen. For example, the number following 2-999 will be 2-000; 1-99-000 will follow 1-99-999.
- The number following 9999999999999 will be 1.

4. Analyze Sample

(1) Mix the whole blood sample thoroughly by inverting the tube.

(2) Set the tube in the Manual CP Unit.

(3) Close the Manual CP Unit cover.

(4) Press the Start Switch to start the analysis.

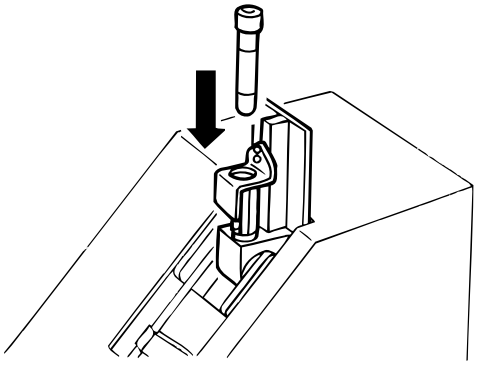


Figure 2-36: Set Sample in the Manual CP Unit

After the sample is aspirated, the analysis begins. You can check the status of each stage of analysis using the Analysis Process screen. To see this screen, press [Status] key in the root menu. Switch to "P2. Analysis Process" using the [→] and [←] keys.

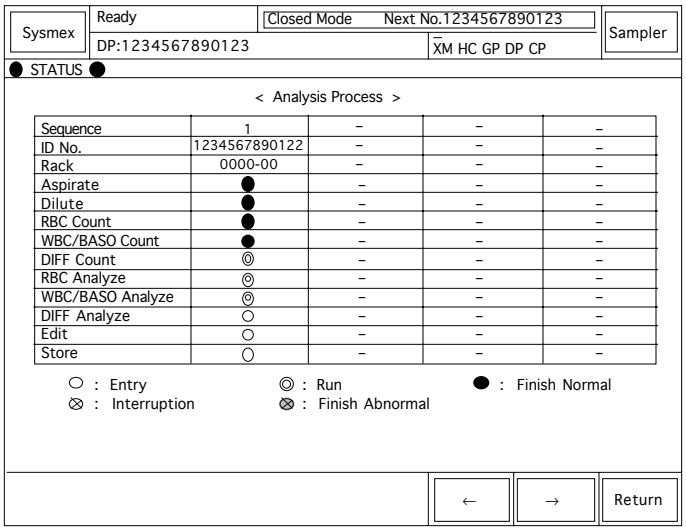


Figure 2-37: Analysis Process Screen (Manual CP/Closed Mode)

6. Display Analysis Results

After analysis is complete (approximately 85 seconds after the sample is aspirated), the results are displayed on the screen.

NOTE: "P" in green backlight is added to the Sample ID No.

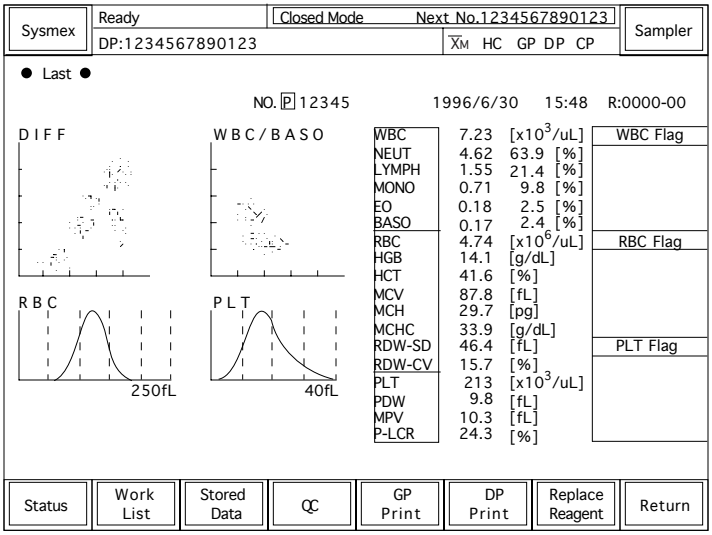


Figure 2-38: Analysis Results Screen (Manual CP Mode)

CAUTION: If all the following conditions are met, the sample is assumed blank and the analysis result will be neither stored nor judged against any flagging criteria.

WBC	<	1.00	x $10^3/\mu L$
RBC	<	0.30	x $10^6/\mu L$
HGB	<	1.0	g/dL
PLT	<	20	x $10^3/\mu L$

7. Output Analysis Results

If automatic output has been set up, the analysis results will be sent to the Graphic Printer, Data Printer, and/or Host Computer.
If automatic output has not been set up, the operator must select the data and destination for output. See *Chapter 4: Result Interpretation/Reports.*

8. Perform Post-Analysis Procedures

Residual blood and reagent can cause detector aperture to clog and protein to build up in aspiration lines. If the instrument is not to be used for a while, press the [Auto Rinse] key in the root menu to execute a background check.

NOTE:	If the [Auto Rinse] key is not displayed on the LCD, press [More] key to change the root menu display.

If no further specimens require processing, return the system to Manual mode as follows:

(1) Press the Next No. keypad in the top line of the LCD. The Sample No. Setting screen will appear.

(2) Press the [Manual Mode] key to select manual analysis mode, and press the [ENTER] key.

5. SHUTDOWN

When instrument shutdown is performed, the detector chambers and manometers are cleaned. You should run the instrument through a shutdown cycle at the end of each day's analyses or at least once every 24 hours if running the instrument continuously.

5.1 Shutdown Procedure

(1) Press the [Shutdown] key from the root menu.

> **NOTE:** If the [Shutdown] key is not displayed on the LCD, press [More] to change the displayed root menus.

(2) The Shutdown Execute window as shown below will appear. Press [Cancel] key to cancel the program.

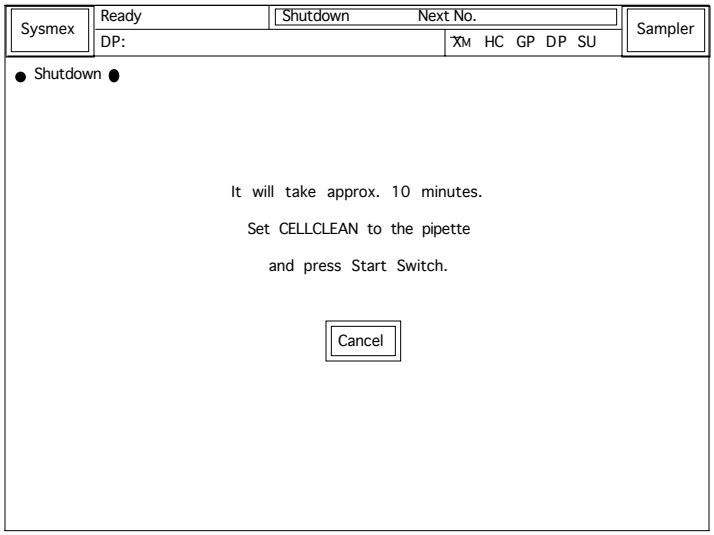


Figure 2-39: Shutdown Execute Window

> **WARNING!** CELLCLEAN (or 5% filtered sodium hypochlorite) is a strong alkaline solution. Avoid contact with it. If you get it on your skin or clothing, immediately wash it off with excess water.

(3) Position the CELLCLEAN [or 5% filtered sodium hypochlorite (bleach)] into the manual aspiration pipette as shown in Figure 2-40; then press the START switch. Do not remove the CELLCLEAN while the READY LED is blinking as CELLCLEAN is being aspirated.

(4) After the READY LED turns off and the alarm beeps three times, remove the CELLCLEAN.

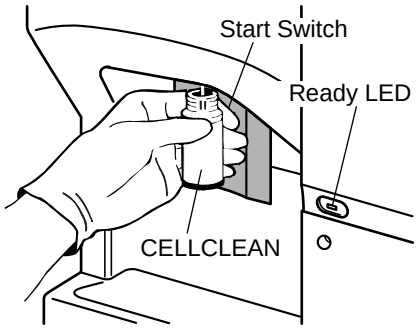


Figure 2-40: Introduce CELLCLEAN

(5) The shutdown sequence will start. During shutdown sequence, "Shutdown in Progress." is displayed on the LCD.

(6) After the shutdown sequence is completed, a continuous beep will sound and the Shutdown Complete screen will appear.

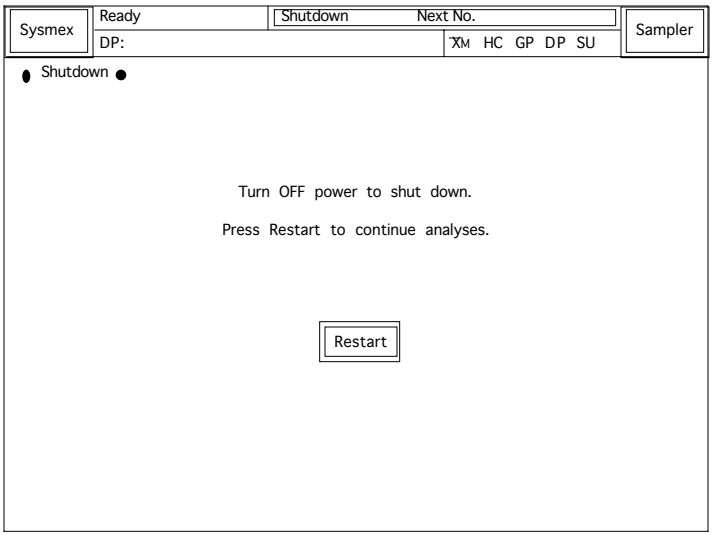


Figure 2-41: Shutdown Complete Screen

(7) If you are going to shutdown the instrument, turn the Main Unit power OFF. Turn the printers off, if attached.

NOTE: If you are going to continue to operate, perform a background check by pressing the [Restart] key displayed on the LCD.

6. TIMER MODE

When timer mode is used, the Pneumatic Unit power automatically turns OFF if the Main Unit does not detect any operation of the Start Switch or the keys on the LCD to cycle the instrument within a preset amount of time. "Not Ready", "PU Off" and "PRESS START SWITCH" messages are displayed in the top lines of LCD. To set, see *Chapter 11: System Setup*.

6.1 Restarting the Pneumatic Unit

To restart the Pneumatic Unit, press the Start Switch.

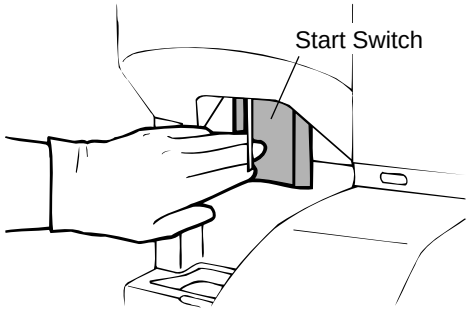


Figure 2-42: Press the Start Switch

CAUTION: If the Main Unit is not in Ready status, the Timer Mode does not function and the Pneumatic Unit power will not turn OFF.

CHAPTER 3 WORK LIST

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   1.1 Order Inquiry Method 3-1

2. EXECUTING A WORK LIST PROGRAM 3-2
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6. BACKUP 3-14

1. INTRODUCTION

The SF-3000 registers ordering analysis information which enables the user to specify the samples to be analyzed.

Order information on 50 samples can be input by LCD touch panel or by transmission from the host computer. In addition, they can be registered by downloading from a floppy disk. This chapter describes registering and processing of analysis information.

Order information includes the followings:
- Rack No.
- Tube Position
- Sample No.
- Analysis Order

NOTE: The order information is applicable for Auto Mode analysis only.

NOTE: When the Work List is set as "Not Used", order inquiry of the Work List will not be performed. To perform order inquiry of the Work List, set the Work List to "Used", using the setting program. Refer to *Chapter 11, Section 6.9: Work List* for information.

1.1 Order Inquiry Method

The analysis operation on a sample will be performed according to analysis information ordered as below:

1. Perform inquiry of the Work List prior to analysis. Analyze the sample according to the order request, if registered.

2. When the analysis order is not registered in Work List for that sample, the SF-3000 analyzes the sample.
   Analysis operation is performed by each order inquiry made by Sample ID No. or Rack-Tube Position No. according to the system setting. Refer to *Chapter 11, Section 6.9 Work List* for the setting.

NOTE: If the data processing system model SF-DPS is installed with the SF-3000, the real-time order inquiry of the host computer can be performed. Contact your Sysmex sales representatives for information.

2. EXECUTING A WORK LIST PROGRAM

Press [Work List] keypad in the Root Menu. The Work List as shown in Figure 3-1 appears. The analysis information is input using this display.

When the Work List screen appears, the second menu also appears in the bottom line. The second menu provides the following processing modes: "Down Load", "Output" and "Delete". These modes can be selected through the LCD touch panel. Refer to the following sections for the procedures.

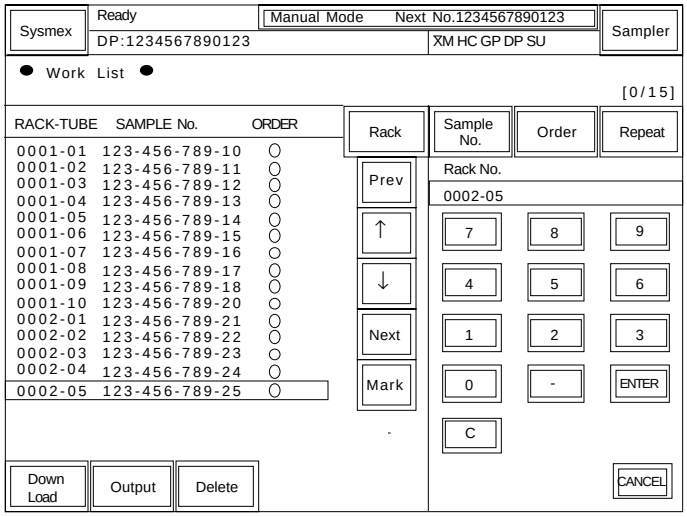

Figure 3-1: Work List Display

2.1 Work List Display

The Work List display contains the following information:

Displayed Items

• RACK-TUBE
  Displays the rack number (1 - 9999) and the tube position number indicates the location of the blood sample tube in the rack (1 - 10).
• SAMPLE No.
  Displays the sample ID number (up to 13 digits).
• ORDER
  Displays the analysis order inquiry and the status of the sample analysis in progress.

Blank	:	Indicates that the sample is not to be analyzed.
Circle (◯)	:	Indicates that the sample is to be analyzed but has not been analyzed.
Double Circle (◎)	:	Indicates that analysis is complete.
Cross (X)	:	Indicates that an analysis error occurred, preventing the completion of sample analysis.

• [#/##]
  Number of marked samples/Number of registered samples in the list is indicated above [Repeat] keypad.

Key Operation

[↑] key : Cursor (displayed in reverse video) moves up one sample. When the cursor is placed on the top line, the page is scrolled down.

[↓] key : Cursor moves down one sample. When the cursor is placed on the bottom line of the LCD, the page is scrolled up.
When the cursor is placed on the bottom line of the list, this key has repeat function. Refer to the description about [Repeat] key in the following section.

[Prev] key : Cursor moves up one page (20 samples).
[Next] key : Cursor moves down one page (20 samples).

[Mark] key : Marks data. Refer to *Section 4.2: Marked Data* in this chapter.

2.2 Data Entry

The Work List display contains the following function keys to enter the order information. Order information can be input on up to 50 samples.

[Rack] key : When this key is pressed, "Rack No." is displayed above the numeric keys. The rack number (4 digits) and the tube position number (1 - 10) can be input with the numeric keys. Place a hyphen between the rack number and the tube position number. See Figure 3-2.

> **NOTE:** Rack-Tube Position No. is a set number.

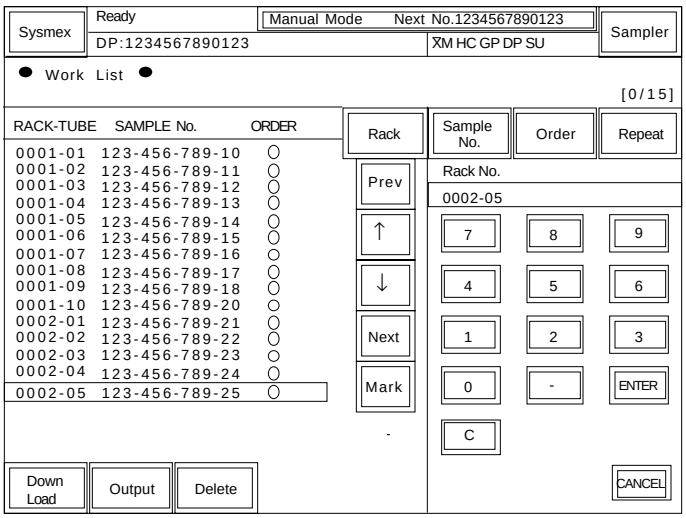

Figure 3-2: Rack - Tube Position No. Input Screen

[Sample No.] key : When this key is pressed, "Sample No." is displayed above the numeric keys as shown in Figure 3-3. Sample numbers up to 13 numerical digits and hyphens can be input.
A hyphen cannot be placed at the beginning or end of the number and two or more hyphens cannot be placed consecutively.

> **NOTE:** If the Sample No. column is left blank with no number entry, a sequential number for Auto mode analysis will be automatically assigned for the sample.

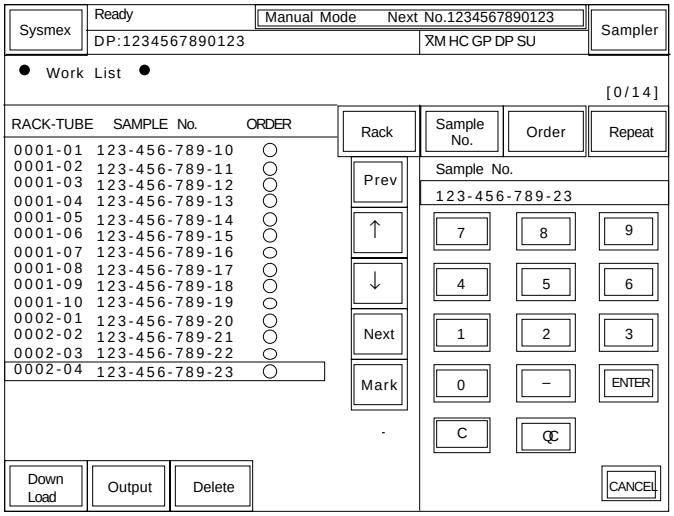

Figure 3-3: Sample No. Input Screen

[Order] key : Analysis order is set by pressing this key.
Pressing this key places or removes a circle (◯) from the sample on which the cursor (displayed in reverse video) is placed. Place a circle to analyze the sample, or remove the circle for not to analyze the sample.

[Repeat] key : When this key is pressed, "Repeat" is displayed above the numeric keys.
Enter the number of samples to enter the order information and press [Enter].
The Rack-Tube and Sample ID No. which are incremented by one to those of the previous sample will be assigned. The analysis order information appears the same as the previous sample. See the example below.

Example)
When the cursor is on a sample with order information;
Rack-Tube: "0001-01", Sample No.: "123-456", Order "○"

Pressing [Repeat], [3], then [ENTER] keypads will assign the following three samples as below:
Rack-Tube: "0001-02", Sample No.: "123-457", Order "○"
Rack-Tube: "0001-03", Sample No.: "123-458", Order "○"
Rack-Tube: "0001-04", Sample No.: "123-459", Order "○"

NOTE: Since the order information can be input on up to 50 samples, a number between 1 and 49 can be accepted after pressing [Repeat] key.

NOTE: When the cursor is placed on the bottom of the list, [↓] key functions as repeat key when pressed, which will assign the Rack-Tube Position No. and the Sample No. incremented by one to those of the previous sample.

NOTE: A number will be carried beyond a hyphen. For example, the Rack-Tube No. following 0001-10 will be 0002-01, 0001-01 will follow 9999-10.

[0] - [9], [–] : Inputs number or a hyphen.

[QC] : Press this key to set the QC samples by registering the QC File No. in which the L-J QC analysis results are stored as control data. For example, press [QC] and [1] keys to specify the QC File No. 01.

[ENTER] : Sets the input values.

[C] : Used as a backspace key to delete one character.

3. DOWNLOAD LIST

With this program you can download order information from a host computer (HC) or floppy disk (FD) to the SF-3000.

3.1 From Host Computer (HC)

You can inquire about order information from the Host Computer using the rack number.

(1) Press [Down Load] keypad. The Down Load window as shown in Figure 3-4 will appear.

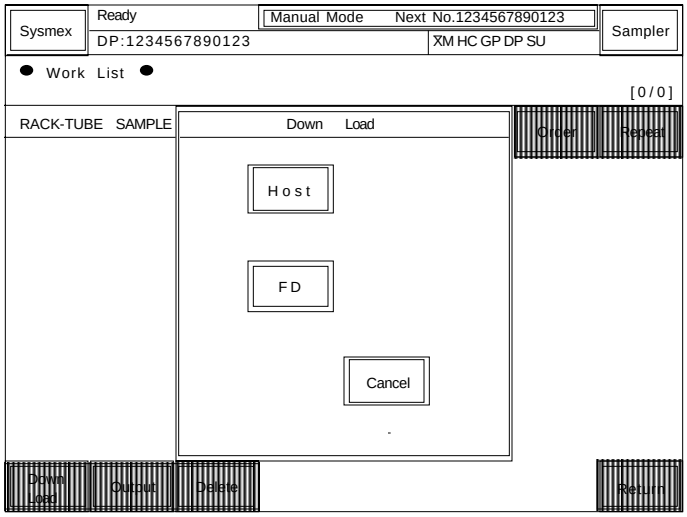

Figure 3-4: Down Load Window

(2) Press the [Host] keypad. The HC Down Load screen as shown in Figure 3-5 will be displayed.

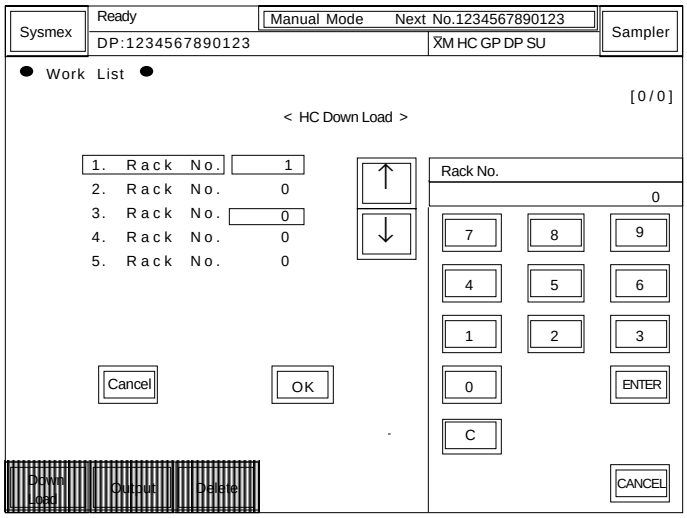

Figure 3-5: HC Down Load Screen

(3) Input the rack number with numeric keypads and press [Enter]. The rack number will be registered, and the cursor will move to the next rack number. Move the cursor by using the [↑] and [↓] keys.

(4) Pressing [Cancel] cancels the down loading and returns to the Work List display. When all rack numbers have been input, press the [OK] key. The order information transmission from the host computer will start.
If rack numbers are not set, the program ends and the instrument returns to the Work List Display screen.

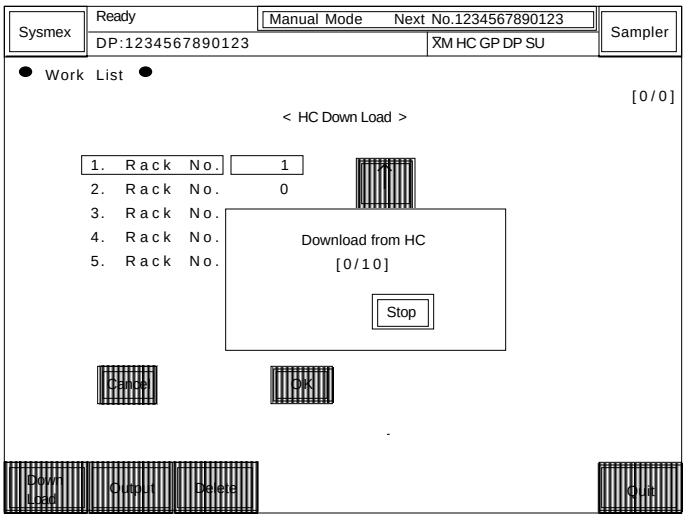

Figure 3-6: HC Down Loading Message Window

3.2 From Floppy Disk (FD)

This program reads order information from a floppy disk, re-utilizing previously backed up order information.

(1) Press [Down Load] keypad. The Down Load window as shown in Figure 3-7 will appear.

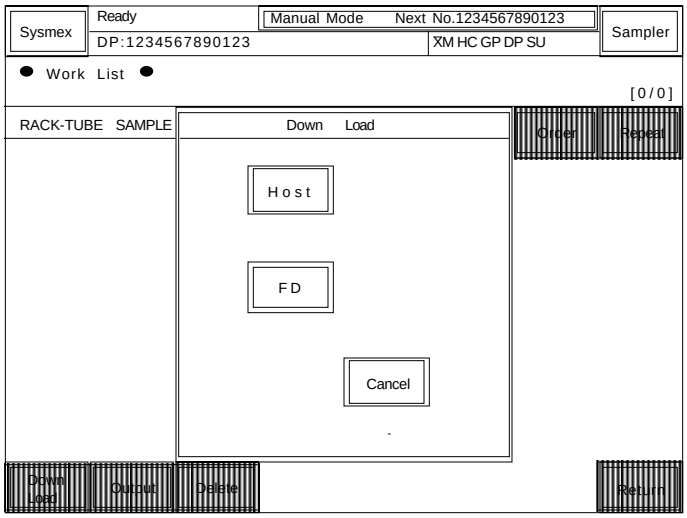

Figure 3-7: Down Load Window

(2) Press the [FD] keypad. The FD Down Load screen as shown in Figure 3-8 will be displayed.

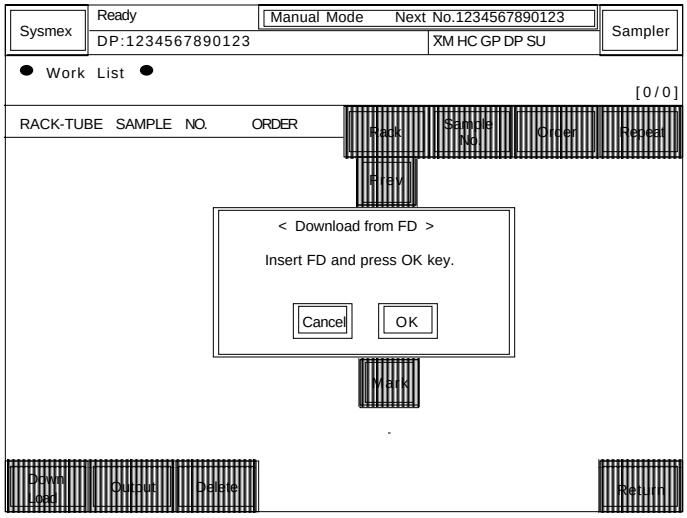

Figure 3-8: FD Down Load Screen

(3) Insert the floppy disk containing the order information file into the floppy disk drive.

(4) Press [OK] key to read the order information file.
Press [Cancel] key to stop the program and return to the List Display screen.

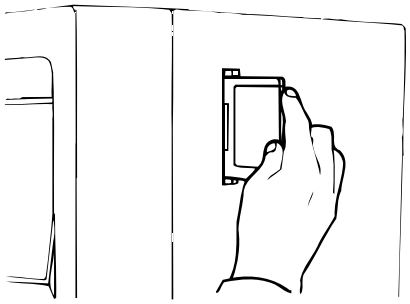

Figure 3-9: Insert Floppy Disk (Main Unit - Right Side)

When a disk is not inserted when pressing [OK] or the disk is unreadable, "FD Read Error" will appear. Press [OK] key to close the window and retry the FD down load using a correct floppy disk, if needed.

Figure 3-10: FD Read Error Window

4. DELETE

You can delete specified order information registered in memory. If you select this menu, the "Delete" submenu appears, enabling you to choose "Current", "Marked" or "All" data.

To delete order information:

(1) Press [Delete] keypad. The Delete window appears as shown in Figure 3-11.

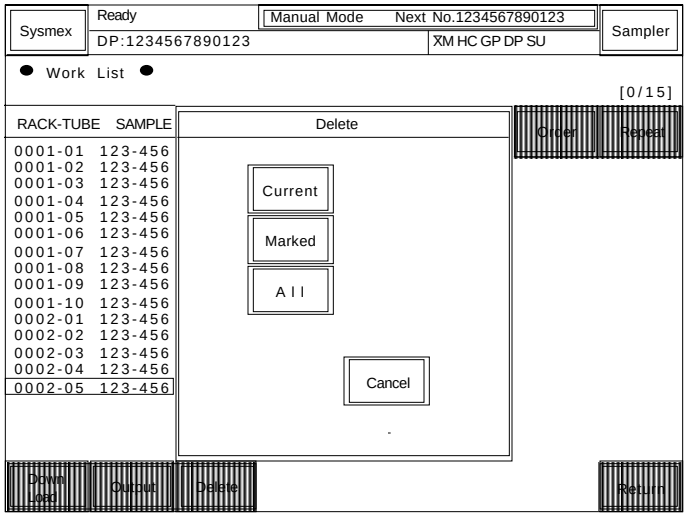

Figure 3-11: Delete Window

(2) Press the desired keypad to specify the data to be deleted.

(3) Press [OK] key to delete the data. Refer to the following sections for the procedure.

4.1 All Data

Use this program to delete all the order information.

(1) Display the Work List on the screen.

(2) Press [Delete] key to display the Delete window.

(3) Press [All] key. The Delete Confirmation window will appear as shown in Figure 3-12 below.

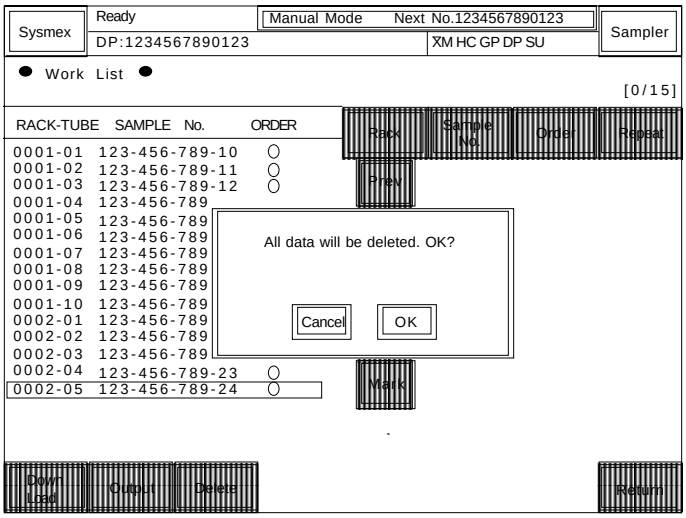

Figure 3-12: Delete (All) Confirmation Window

(4) Press [OK] to delete all order information. Program deletes the data.

4.2 Marked Data

This program specifies marked data for deletion.

(1) Display the Work List on the screen.

(2) Press the [Mark] keypad to mark the data to be deleted. The Mark Data screen as shown below will appear.

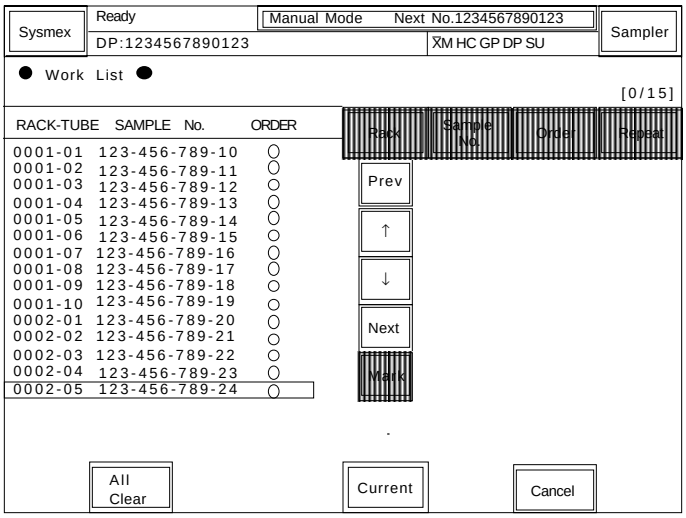

Figure 3-13: Mark Data Screen

Key Operation:

[All Clear] : Clears existing yellow marks.
[Current] : Marks the data the cursor is on with a yellow mark. If the data was already marked with a yellow mark, the mark is cleared.
[Cancel] : Returns to the Work List display.

(3) Press [Delete] key to display the Delete window.

(4) Press [Marked] key. The Delete Confirmation window will appear.

(5) Press [OK] to delete the marked data. Program deletes the data.

4.3 Current Data

The order information that is deleted is specified by using the cursor.

(1) Display the Work List on the screen.

(2) Use [↑], [↓], [Prev.] and [Next] keys to move the cursor and select the data to be deleted.

(3) Press [Delete] key to display the Delete window.

(4) Press [Current] key. The Delete Confirmation window will appear.

(5) Press [OK] to delete the data with the cursor on it. Program deletes the data.

5. GP OUTPUT

You can print out the list of order information to a Graphic Printer.

(1) Press [Output] keypad. The Select Device window appears as shown in Figure 3-14.

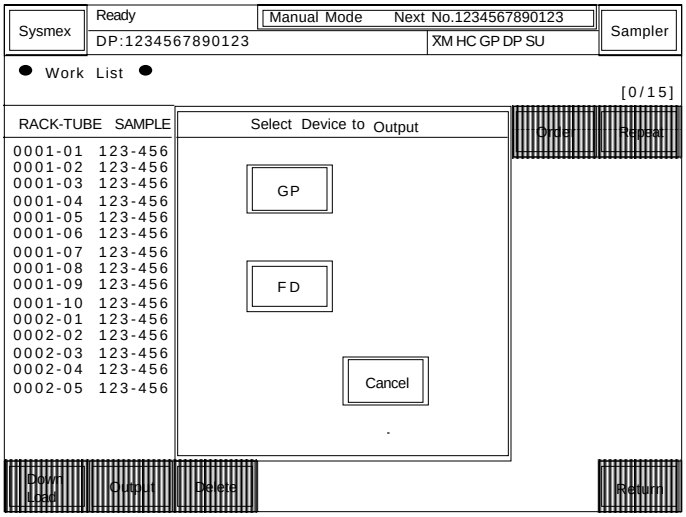

Figure 3-14: Select Device Window

(2) Press the [GP] keypad. The GP Output window appears as shown in Figure 3-15.

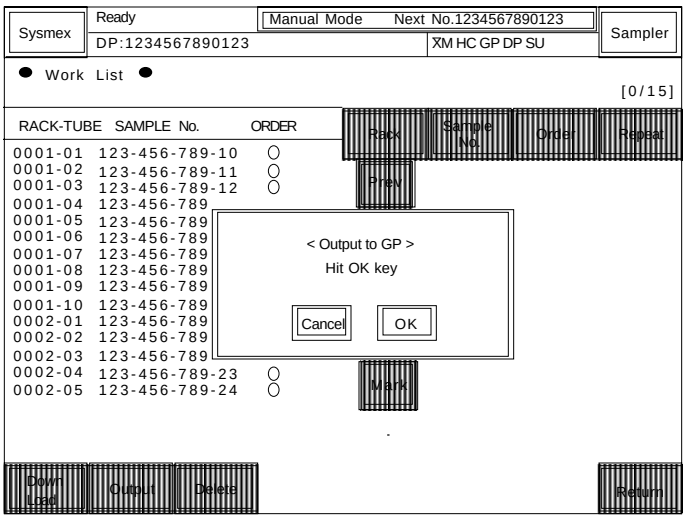

Figure 3-15: GP Output Window

(3) Press [OK] key to print out the order information data to the Graphic Printer. Press [Cancel] key to stop the program and return to the Work List display.

6. BACKUP

You can copy registered order information onto a floppy disk.

NOTE: The floppy disk should be pre-formatted in MS-DOS 1.44 MB format using "Mainte." - "Format FD" program. Refer to *Chapter 5, Section 10: Format FD* for the procedure. An unused, commercially pre-formatted MS-DOS 1.44 MB floppy disk also can be used.

NOTE: All the order information data will be copied to a floppy disk. If there is any order information data already written on the floppy disk, the data will be replaced.

(1) Press [Output] keypad. The Select Device window appears as shown in Figure 3-16.

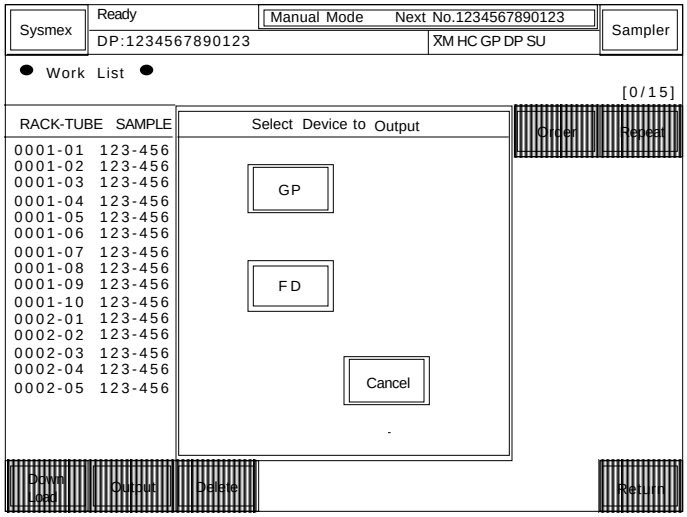

Figure 3-16: Select Device Window

(2) Press the [FD] keypad. The FD Output window appears.

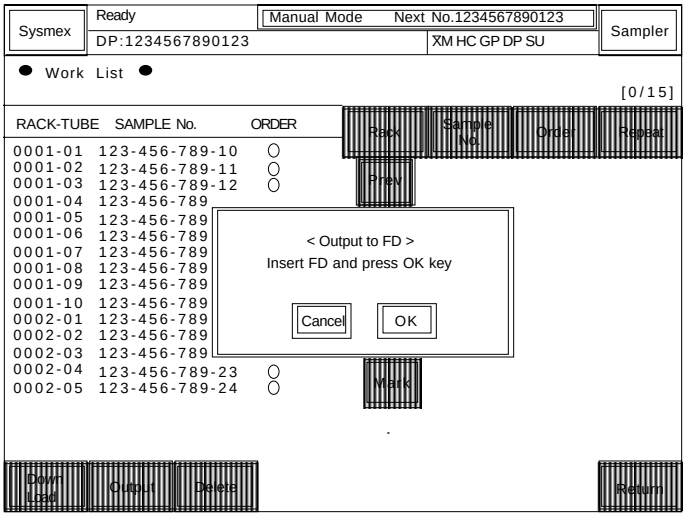

Figure 3-17: FD Output Window

(3) Insert a floppy disk into the floppy disk drive.

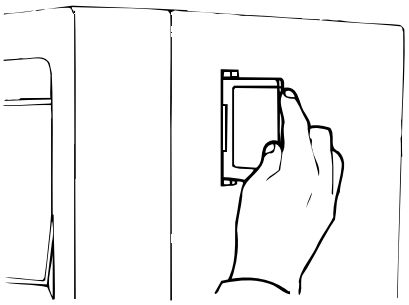

Figure 3-18: Insert Floppy Disk (Main Unit - Right Side)

(4) Press [Cancel] key to cancel the program and return to the Work List display. Press [OK] key to store the order information data on a floppy disk. The FD Writing Window will appear.

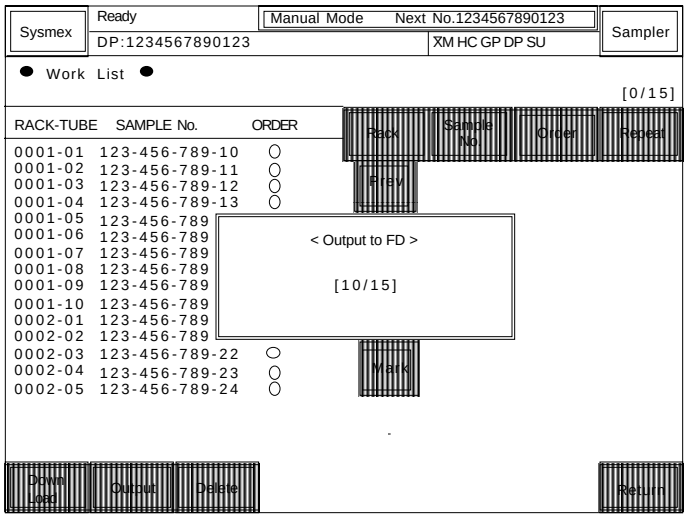

Figure 3-19: FD Writing Window

(5) When writing the data is completed, the display returns to Work List display.

CHAPTER 4 RESULT INTERPRETATION/ REPORTS

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1. INTRODUCTION

The SF-3000 is used to analyze and screen whole blood samples, and to store and reproduce the sample results. This chapter explains the screen displays, output and processing of analysis results in the Stored Data program.

This chapter consists of the following major sections:

INTERPRETIVE MESSAGES
A significant feature of the SF-3000 is the use of Interpretive (IP) messages. This section describes the various messages employed by the system, their meaning, and the conditions in which they appear.

ANALYSIS RESULT DISPLAYS
In the Stored Data program, analysis results are displayed in list format and graphic format. Here it is explained how to select these formats, the items displayed in each format, and the meaning of the items displayed.

PROCESSING OF ANALYSIS DATA
In the Stored Data program, various manipulations of displayed data are possible - changing the type of data displayed or the order it is displayed in, changing analysis data, etc. How to manipulate data using this program is explained.

AUTO OUTPUT
Stored sample data can be printed out automatically by a Data Printer or Graphic Printer, or transmitted automatically to a Host Computer.

STORED DATA OUTPUT
Stored marked sample data and date-specified data can be output to Data Printer, Graphic Printer and/or Host Computer. Also these data can be output to a floppy disk as a back up . This section explains the procedures for these outputs.

2. INTERPRETIVE (IP) MESSAGES

The SF-3000 analyzes, displays and prints hematology information in a format designed to aid in the separation of POSITIVE or NEGATIVE data results. All analyzed samples without analysis errors can be separated into a POSITIVE and NEGATIVE category according to preset criteria.
The system bases its judgment on comprehensive surveys of numerical data, particle size distribution, scattergrams, etc., and provides easy to understand flags/messages indicating the instruments findings. These flags/messages are referred to as "IP (Interpretive Program) messages."

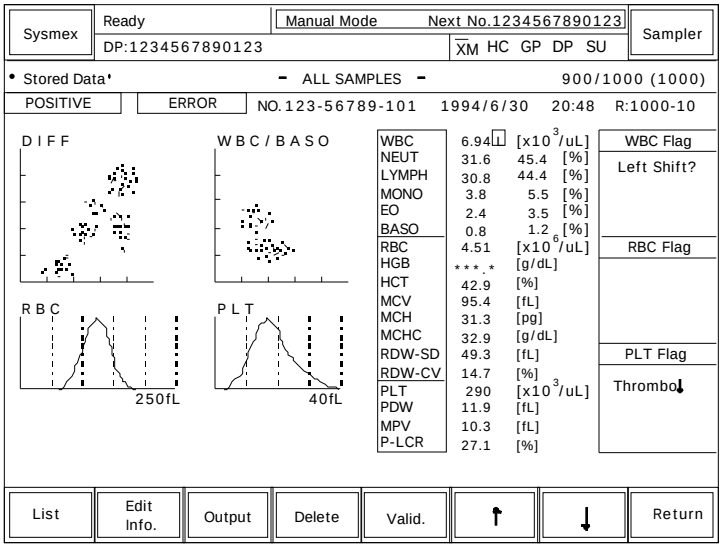


Figure 4-1: IP Message Screen

POSITIVE (red back-light) : A POSITIVE result indicates a sample is judged abnormal according to preset criteria for analysis numerical values and cell morphology.

NEGATIVE (green back-light) : A NEGATIVE result indicates that the sample is normal, i.e., has no analysis errors or IP messages.

The system sub-categorizes and flags POSITIVE results as "Diff.", "Morph." and/or "Count" during WBC, RBC and PLT analysis. These flags appear when abnormal cell population is detected during computer analysis of the particle size distribution, scattergrams and 23 parameters.

Diff. : Indicates abnormality in the WBC differential parameters.
Morph. : Indicates abnormal cell morphology.
Count : Indicates abnormality in the blood cell numerical count.

These sub-categories appear below the POSITIVE flag.

Two types of IP message flags, "Abnormal" and "Suspect", appear in the WBC, RBC and PLT boxes on the LCD screen.

Abnormal IP messages : indicate that the sample is defined abnormal. With a few exceptions, all criteria for Abnormal IP messages can be preset by the operator.
Suspect IP messages : indicate that there is a possibility that the sample is abnormal.

NOTE: All IP messages are intended for investigational use in the clinical laboratory ONLY; they should NOT be reported on patient records. IP messages are provided to alert the operator to the possibility of specific abnormalities, which the operator should confirm by examining the analysis results.

When an IP message is present, other subsequent data is considered to be unreliable because of the abnormality indicated by the IP message. Asterisk (with yellow backlight) appears to the right of such data, or the data is dashed out, as shown below.

Table 4-1: Data to which Asterisk is Affixed

Message	RBC HCT MCV MCH MCHC	HGB MCH MCHC	PLT MPV PDW P-LCR	WBC	NEUT		LYMPH		MONO		EO		BASO	
					%	#	%	#	%	#	%	#	%	#
RBC Agglutination?	*													
Turbidity/HGB Interf?		*												
WBC Abn Scattergram (Morph, DIFF, WBC/BASO)				---.--	---.-	---.--	---.-	---.--	---.-	---.--	---.-	---.--	---.-	---.--
RBC Abn Scattergram (Morph)	*													
PLT Abn Scattergram (Morph)			*											
NRBC/PLT Clumps?			*	*	*	*	*	*	*		*		*	
Blasts/A-Lymph?					*	*	*	*	*	*			*	*
Immature Gran?					*	*			*	*			*	*
Aty/Abn Lympho?					*	*	*	*	*	*				

NOTE: When "WBC Abn Scattergram" is reported, only the affected parameters are dashed out.

The IP messages used by the SF-3000 are listed on the following tables.

> **NOTE:** A [C] following the item number means that the message will appear with samples analyzed in the Capillary Mode.

Item No. refers to the code displayed on the IP message screen in Stored Data (See *Section 3.6* in this chapter).

Table 4-2: WBC IP Messages

WBC IP MESSAGES				
"Abnormal" messages				
Item No.	Message	Abbreviation	Meaning	Category
1	WBC Abn Scattergram	WBC Abn Scg	WBC abnormal scattergram	Morph.
2	Neutropenia	Neutro↓	Low neutrophil count	Diff.
3	Neutrophilia	Neutro↑	High neutrophil count	Diff.
4	Lymphopenia	Lympho↓	Low lymphocyte count	Diff.
5	Lymphocytosis	Lympho↑	High lymphocyte count	Diff.
6	Monocytosis	Mono↑	High monocyte count	Diff.
7	Eosinophilia	Eo↑	High eosinophil count	Diff.
8	Basophilia	Baso↑	High basophil count	Diff.
9 [C]	Leukocytopenia	Leuko↓	Low leukocyte count	Count
A [C]	Leukocytosis	Leuko↑	High leukocyte count	Count
"Suspect" messages				
Item No.	Message	Abbreviation	Meaning	Category
1	Blasts/A-Lymph?	Blasts/A-Ly?	Possibility that blasts, atypical lymphocytes, or abnormal lymphocytes are present	Morph.
2	Immature Gran?	Imm Gran?	Possibility that immature granulocytes are present	Morph.
3	Left Shift?	Left Shift?	Possibility of left shift	Morph.
4	Aty/Abn Lympho?	Aty/Abn Ly?	Possibility that atypical lymphocytes or blasts are present	Morph.
6	NRBC/PLT Clumps?	NRBC/PLTC?	Possibility that nucleated RBC or PLT clumps are present	Morph. Count

WBC IP Message Criteria

1. Normal Analysis

IP messages do not appear with the following data:

- QC analysis data
- Analysis data for calibration
- Background check data
- PDA check data
- Blank data
- "LOW BLOOD VOLUME" data

WBC Suspect messages are not generated for the WBC# < 0.6 x $10^3/\mu L$.

If any parameter result that is used as the flagging criterion cannot be obtained due to an error, the IP messages will not appear (i.e. parameters appearing as "****", "----" and "++++").

2. Capillary Mode Analysis

For Capillary mode analysis, the conditions applicable on IP messages given for normal analysis above also apply. In addition, IP messages **only** appear for the CBC-8 parameters, and **only** "POSITIVE" IP messages appear.

Table 4-3: RBC IP Messages

RBC IP MESSAGES				
"Abnormal" messages				
Item No.	Message	Abbreviation	Meaning	Category
1	RBC Abn Distribution	RBC Abn Dst	WBC abnormal distribution	Morph.
2	Dimorphic Population	Dimorph Pop	Double-peak RBC distribution (superimposed distributions)	Morph.
3	Anisocytosis	Aniso	Anisocytosis	Morph.
4 (C]	Microcytosis	Micro	Microcytosis	Morph.
5 [C]	Macrocytosis	Macro	Macrocytosis	Morph.
6 [C]	Hypochromia	Hypochromia	Hypochromia	Morph.
7 [C]	Anemia	Anemia	Anemia	Count
8 [C]	Erythrocytosis	Erythro ↑	Erythrocytosis	Count
"Suspect" messages				
Item No.	Message	Abbreviation	Meaning	Category
1	RBC Agglutination?	RBC Agglut?	Possibility of RBC agglutination	Count
2	Turbidity/HGB Interf?	Turb/HGB?	Possibility of HGB interference due to anemia, etc.	Count
3	Iron Deficiency	Iron Def?	Possibility of iron deficiency exists	Morph.
4	HGB Defect?	HGB Defect?	Possibility of HGB abnormality	Morph.
5	Fragments?	Fragments?	Possibility of fragmented RBCs	Morph.

RBC IP Message Criteria

1. Normal Analysis

IP messages do not appear with the following data:
- QC analysis data
- Analysis data for calibration
- Background check data
- PDA check data
- Blank data
- "LOW BLOOD VOLUME" data
- Data with RBC# error ("****") or analysis error ("----")

"Abnormal" or "Suspect" messages are not generated for the RBC# < 0.5 x 10^6/µL, with the exception of RBC ABN Distrib.

If any parameter result that is used as the flagging criterion cannot be obtained due to an error, the IP messages will not appear (i.e. parameters appearing as "****", "----" and "++++").

2. Capillary Mode Analysis

For Capillary mode analysis, the conditions applicable on IP messages given for normal analysis above also apply. In addition, IP messages **only** appear for the CBC-8 parameters, and **only** "POSITIVE" IP messages appear.

Table 4-4: PLT IP Messages

PLT IP MESSAGES				
"Abnormal" messages				
Item No.	Message	Abbreviation	Meaning	Category
1	PLT Abn Distribution	PLT Abn Dst	PLT distribution abnormality (Morph.) Analysis results abnormality (Count)	Morph. Count
2 (C]	Thrombocytopenia	Thrombo↓	Thrombocytopenia	Count
3 [C]	Thrombocytosis	Thrombo↑	Thrombocytosis	Count
"Suspect" messages				
Item No.	Message	Abbreviation	Meaning	Category
5	NRBC/PLT Clumps?	NRBC/PLT C?	Possibility that nucleated RBC or PLT Clumps are present.	Morph. Count

PLT IP Message Criteria

1. Normal Analysis

IP messages do not appear with the following data:
- QC analysis data
- Analysis data for calibration
- Background check data
- PDA check data
- Blank data
- "LOW BLOOD VOLUME" data
- Data with PLT# error ("****") or analysis error ("----")

If any parameter result that is used as the flagging criterion cannot be obtained due to an error, the IP messages will not appear (i.e. parameters appearing as "****", "----" and "++++").

2. Capillary Mode Analysis

For Capillary mode analysis, the conditions applicable on IP messages given for normal analysis above also apply. In addition, IP messages **only** appear for the CBC-8 parameters, and **only** "POSITIVE" IP messages appear.

3. LIST DISPLAY/STORED DATA

The SF-3000 can store the analysis data, together with scattergrams, for up to 1000 samples in a hard disk. The stored analysis data is displayed in list form by using "List Display" of "Stored Data" program.

NOTE:
- The type of data displayed can be selected. Refer to *Section 7: Select Display.*
- The List Display can be arranged in chronological order of analysis or in order of the Sample ID No. Refer to *Section 9*: *Sort Stored Data.*

To execute Stored Data program:

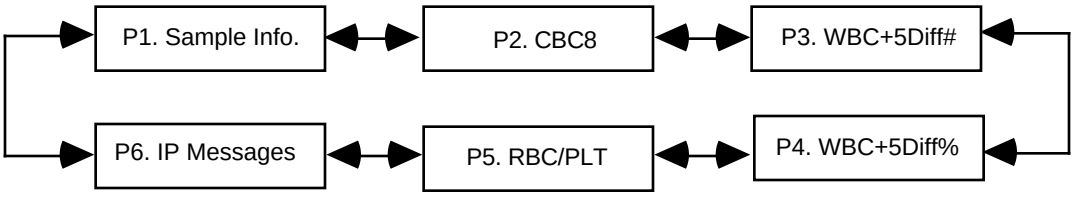
(1) Press the [Stored Data] keypad in the Root Menu.

(2) The Sample Information Screen will appear, together with the second menu. This menu consists of the following processing modes: "Graphic Display", "Search", "Sort", "Select Display", "Output", "Valid.", "Edit Info." and "Delete". These modes can be selected by pressing corresponding keypad on the LCD touch panel.

NOTE:
- "Graphic Display" keypad is displayed when the list display appears on the screen, and it is replaced by "List Display" keypad when the graphic display is on the screen.
- "Search", "Sort" and "Select Display" menus are not available on the Graphic Display.

List Display Selection:

There are 6 pages of List Display. Use the [→] and [←] keys to switch pages.



List Screen Key Operation:

[↑] key : Moves cursor (displayed in reverse video) up one sample. When the cursor is placed on the top line, the page is scrolled down.

[↓] key : Cursor moves down one sample. When the cursor is placed on the bottom line, the page is scrolled up.

[→], [←] keys : Switch pages.

[Prev] key : Cursor moves up one page (20 samples).

[Next] key : Cursor moves down one page (20 samples).

[Mark] key : Marks data. Refer to *Section 6: Mark Data*.

3.1 Sample Information Screen (Page 1)

This screen displays information about samples analyzed, and appears initially when the [Stored Data] key is pressed.

To switch to this screen from "P6. IP Messages", press [→] key. To switch to this screen from "P2. CBC8", press [←] key.

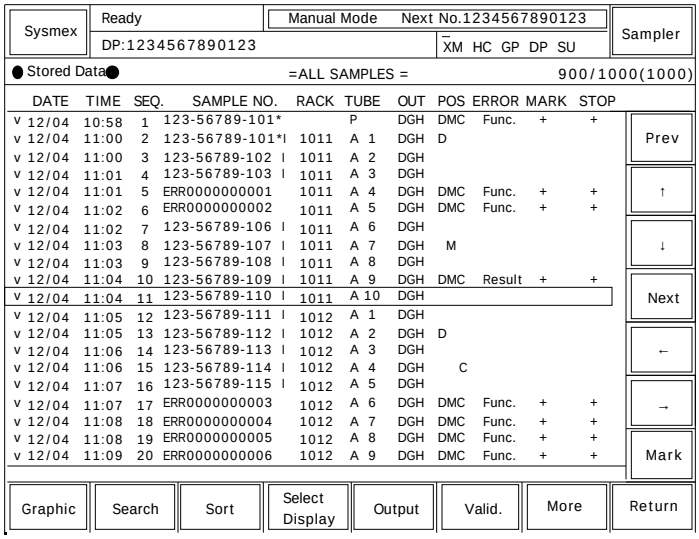


Figure 4-2: Sample Information Screen (P1)

1) "v" (validated) Mark
Indicates that this data is validated. Refer to *Section 5: Data Validation* in this chapter.

2) DATE
Date when the analysis occurred.

3) TIME
Time analysis results were received.

4) SEQ.
Order (numbered) in which data were received after the instrument power turned ON.

5) SAMPLE NO.
Sample No., as read by bar code reader or input by operator.

*	:	Indicates there is another sample with the same sample ID number on the same date.
I	:	Appears on the right of Sample No., indicates Sample No. was read by bar code reader.

NOTE: If the ID bar code reader cannot read a Sample No., an error code "ERR0000000001" will appear in the Sample No. column, and the "I" mark will be backlit in red. The error code numbers will go up in sequence ("...002", "...003", etc.) on subsequent occasions when the bar code reader cannot read a Sample No.
The code will restart from "ERR0000000001" after the instrument power turns OFF.

6) RACK
Rack No. of the analyzed sample.

7) TUBE
Mode in which sample was analyzed and sampler analysis tube position No.

A	:	Sample analyzed in auto (sampler) mode.
C	:	Sample analyzed in capillary mode.
P	:	Sample analyzed in closed mode or manual CP mode.
1-10	:	Tube position No.
E (backlit in red)	:	Appears to left of the Tube Position No. Indicates sample analysis error occurred.

8) OUT
Indicates that the data has not yet been output to a device. Disappears when data is output.

D (backlit in yellow)	:	Data Printer
G (backlit in yellow)	:	Graphic Printer
H (backlit in yellow)	:	Host Computer

9) POS
Indicates abnormal cell analysis or cell morphology.
There are 4 categories:

D (Diff.)	:	Indicates abnormality in WBC differential parameters.
M (Morph.)	:	Indicates abnormal cell morphology.
C (Count)	:	Indicates abnormality in blood cell count.
Mod (Modified)	:	Indicates sample of which POSITIVE judgment was changed manually to NEGATIVE by operator.

10) ERROR
Indicates analysis error. There are two categories:

Func.	:	Indicates analysis error, excluding the ID read errors and the sample errors explained below.
Result	:	Indicates analysis error caused by the sample, such as "SAMPLE NOT ASP ERROR", "LOW BLOOD VOLUME" or "LOW COUNT ERROR".

11) MARK

Indicates that the sample data is outside Mark Limits.

+ (backlit in yellow) : Over upper limit
– (backlit in yellow) : Below lower limit

12) STOP

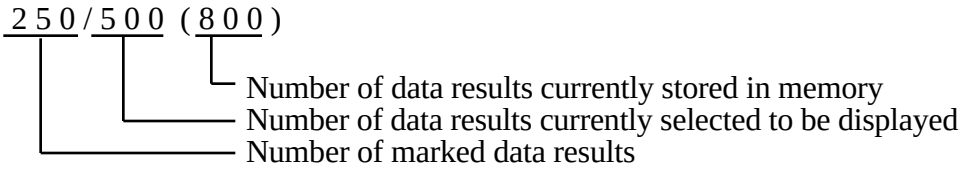
Indicates that the sample data is outside the Sampler Stop Limits.

+ (backlit in red) : Over upper limit
– (backlit in red) : Below lower limit

13) Number of Stored Data

Indicates memory function and the amount of data stored in the memory.

Example)


250/500 (800)
Number of data results currently stored in memory
Number of data results currently selected to be displayed
Number of marked data results

3.2 CBC8 Screen (Page 2)

This screen lists the analysis data for 8 CBC parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC and PLT.

To switch to this screen from "P1. Sample Info.", press [→] key. To switch to this screen from "P3. WBC+5Diff#", press [←] key.

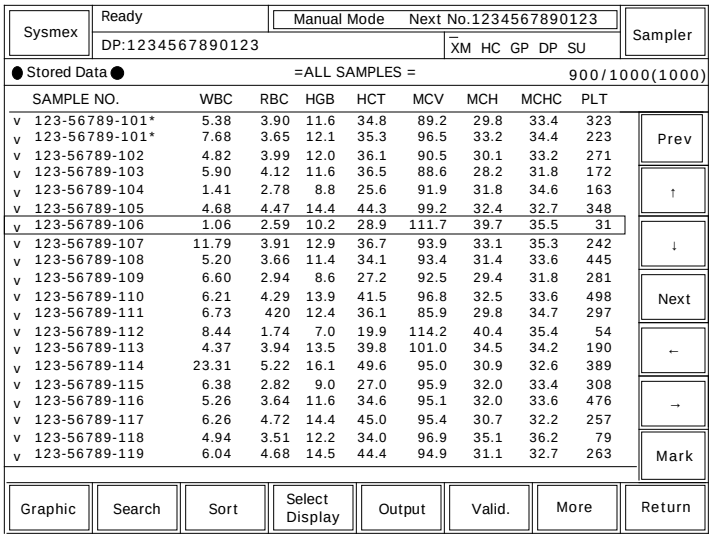


Figure 4-3: CBC8 Screen (P2)

1) "v" (validated) Mark
Indicates that this data is validated. Refer to *Section 5: Data Validation* in this chapter.

2) SAMPLE NO.
Sample No., as read by bar code reader or input by the operator.

3) Indications
The following indications appear to the right of analysis data:

① ! (backlit in red):
Indicates that the data is outside the Critical Limits.
② * (backlit in red):
Indicates that the data is outside the Linearity Limits.
③ +, – (backlit in red):
Indicates that the data is outside the Sampler Stop Limits.
④ * (backlit in yellow):
Indicates that the data is unreliable because of an abnormality detected in the sample.
⑤ +, – (backlit in yellow):
Indicates that the data is outside the Mark Limits.

NOTE: The above indications are listed on the priority basis.

3.3 WBC+5Diff# Screen (Page 3)

This screen lists the WBC count and the absolute values for the following 5DIFF parameters: NEUT#, LYMPH#, MONO#, EO# and BASO#.

To switch to this screen from "P2. CBC8", press [→] key. To switch to this screen from "P4. WBC+5Diff%", press [←] key.

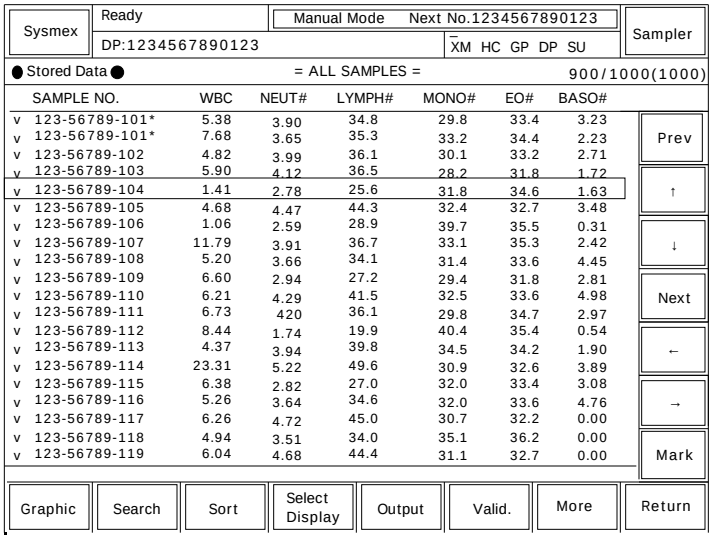


Figure 4-4: WBC+5Diff# Screen (P3)

1) "v" (validated) Mark
Indicates that this data is validated. Refer to *Section 5: Data Validation* in this chapter.

2) SAMPLE NO.
Sample No., as read by bar code reader or input by the operator.

3) Indications
The following indications appear to the right of analysis data:

① ! (backlit in red):
Indicates that the data is outside the Critical Limits.
② * (backlit in red):
Indicates that the data is outside the Linearity Limits.
③ +, – (backlit in red):
Indicates that the data is outside the Sampler Stop Limits.
④ * (backlit in yellow):
Indicates that the data is unreliable because of an abnormality detected in the sample.
⑤ +, – (backlit in yellow):
Indicates that the data is outside the Mark Limits.

NOTE: The above indications are listed on the priority basis.

3.4 WBC+5Diff% Screen (Page 4)

This screen lists the WBC count and the percent values for the following 5DIFF parameters: NEUT%, LYMPH%, MONO%, EO% and BASO%.

To switch to this screen from "P3. WBC+5Diff#", press [→] key. To switch to this screen from "P5. RBC/PLT", press [←] key.

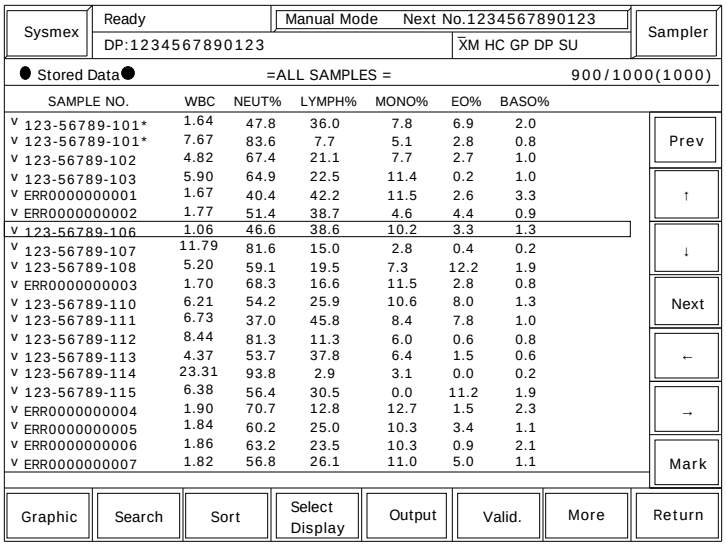


Figure 4-5: WBC+5Diff% Screen (P4)

1) "v" (validated) Mark
Indicates that this data is validated. Refer to *Section 5: Data Validation* in this chapter.

2) SAMPLE NO.
Sample No., as read by bar code reader or input by the operator.

3) Indications
The following indications appear to the right of analysis data:

① ! (backlit in red):
Indicates that the data is outside the Critical Limits.
② * (backlit in red):
Indicates that the data is outside the Linearity Limits.
③ +, – (backlit in red):
Indicates that the data is outside the Sampler Stop Limits.
④ * (backlit in yellow):
Indicates that the data is unreliable because of an abnormality detected in the sample.
⑤ +, – (backlit in yellow):
Indicates that the data is outside the Mark Limits.

NOTE: The above indications are listed on the priority basis.

3.5 RBC/PLT Screen (Page 5)

This screen lists the following RBC and PLT analysis data: MCV, RDW-SD, RDW-CV, PDW, MPV and P-LCR.

To switch to this screen from "P4. WBC+5Diff%", press [→] key. To switch to this screen from "P6. IP Messages", press [←] key.

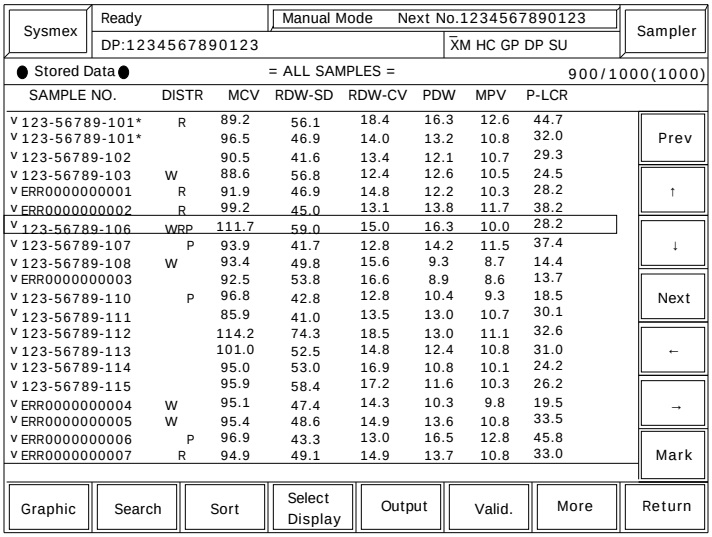


Figure 4-6: RBC/PLT Screen (P5)

1) "v" (validated) Mark
Indicates that this data is validated. Refer to *Section 5: Data Validation* in this chapter.

2) SAMPLE NO.
Sample No., as read by bar code reader or input by the operator.

3) DISTR
Indicates that the sample has abnormal particle size distribution or scattergram.

W (backlit in yellow) : abnormal WBC scattergram
R (backlit in yellow) : abnormal RBC particle size distribution
P (backlit in yellow) : abnormal PLT particle size distribution

4) Indications

The following indications appear on the right of analysis data:

① ! (backlit in red):
Indicates that the data is outside the Critical Limits.
② * (backlit in red):
Indicates that the data is outside the Linearity Limits.
③ +, – (backlit in red):
Indicates that the data is outside the Sampler Stop Limits.
④ * (backlit in yellow):
Indicates that the data is unreliable because of an abnormality detected in the sample.
⑤ +, – (backlit in yellow):
Indicates that the data is outside the Mark Limits.

NOTE: The above indications are listed on the priority basis.

3.6 IP Messages Screen (Page 6)

This lists the WBC, RBC and PLT IP Messages with Message Item Numbers.
To switch to this screen from "P5. RBC/PLT", press [→] key. To switch to this screen from "P1. Sample Information", press [←] key.

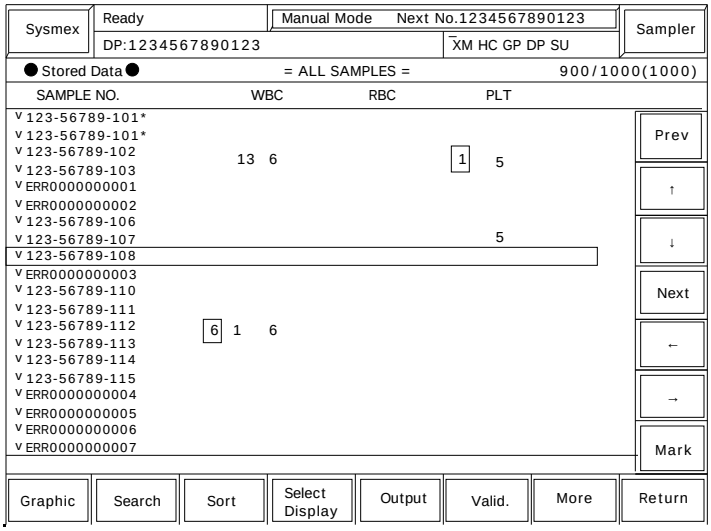


Figure 4-7: IP Messages Screen (P6)

1) "v" (validated) Mark
Indicates that this data is validated. Refer to *Section 5: Data Validation* in this chapter.

2) SAMPLE NO.
Sample No., as read by bar code reader or input by the operator.

3) Message Item Number

Backlit in red: "Abnormal" IP message
No backlit : "Suspect" IP message

Item No.	WBC Abnormal Messages	Abbreviation
1	WBC Abn Scattergram	WBC Abn Scg
2	Neutropenia	Neutro↓
3	Neutrophilia	Neutro↑
4	Lymphopenia	Lympho↓
5	Lymphocytosis	Lympho↑
6	Monocytosis	Mono↑
7	Eosinophilia	Eo↑
8	Basophilia	Baso↑
9 [C]	Leukocytopenia	Leuko↓
A [C]	Leukocytosis	Leuko↑
Item No.	**WBC Suspect Messages**	**Abbreviation**
1	Blasts/A-Lymph?	Blasts/A-Ly?
2	Immature Gran?	Imm Gran?
3	Left Shift?	Left Shift?
4	Aty/Abn Lympho?	Aty/Abn Ly?
6	NRBC/PLT Clumps?	NRBC/PLTC?
Item No.	**RBC Abnormal Messages**	**Abbreviation**
1	RBC Abn Distribution	RBC Abn Dst
2	Dimorphic Population	Dimorph Pop
3	Anisocytosis	Aniso
4 (C]	Microcytosis	Micro
5 [C]	Macrocytosis	Macro
6 [C]	Hypochromia	Hypochromia
7 [C]	Anemia	Anemia
8 [C]	Erythrocytosis	Erythro↑
Item No.	**RBC Suspect Messages**	**Abbreviation**
1	RBC Agglutination?	RBC Agglut?
2	Turbidity/HGB Interf?	Turb/HGB?
3	Iron Deficiency	Iron Def?
4	HGB Defect?	HGB Defect?
5	Fragments?	Fragments?
Item No.	**PLT Abnormal Messages**	**Abbreviation**
1	PLT Abn Distribution	PLT Abn Dst
2 (C]	Thrombocytopenia	Thrombo↓
3 [C]	Thrombocytosis	Thrombo↑
Item No.	**PLT Suspect Messages**	**Abbreviation**
5	NRBC/PLT Clumps?	NRBC/PLTC?

4. GRAPHIC DISPLAY

This program displays scattergrams and particle size distribution for the data analyzed and stored on the hard disk. The Graphic screen displays DIFF scattergram, WBC/BASO scattergram, RBC distribution, PLT distribution, along with data on 23 analysis parameters, sample number and IP messages.

To display Graphic screen:

(1) Press the [Stored Data] keypad in the root menu. The List Display with second menu keys will appear.

(2) Use [↑], [↓], [Prev], and [Next] keys to move the cursor to select a sample to be displayed graphically.

(3) Press the [Graphic] keypad in the second menus. The Graphic screen as shown in Figure 4-8 appears.

In the Graphic screen, pressing the [↑] key will switch to a display of the results for the preceding sample in the List screen, and pressing the [↓] key will switch to a display of the results for the next sample on the List screen.

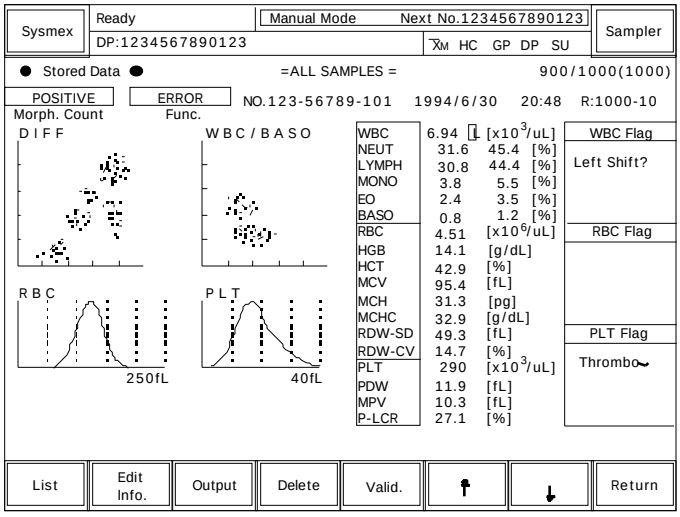


Figure 4-8: Graphic Screen

1) POSITIVE/NEGATIVE

POSITIVE (backlit in red) :
This appears in the top left corner of the screen if the analysis data or cell morphology is abnormal. Below the POSITIVE the following categories appear:

Diff.	:	Indicates abnormality in WBC differential parameters.
Morph.	:	Indicates abnormality in blood cell morphology.
Count	:	Indicates abnormality in blood cell count.

NEGATIVE (backlit in green) :
This appears in the top left corner of the screen if there are no abnormalities or analysis errors (except ID read errors).
"Modified" appears below the NEGATIVE for the sample of which the POSITIVE judgment was changed manually to the NEGATIVE by the operator.

2) ERROR:

[ERROR] (in red box) :
This key appears on the right of POSITIVE/NEGATIVE if any analysis error has occurred. Below the [ERROR] the following error categories appear.

Func.	:	Indicates analysis error, excluding the ID read errors and the sample errors explained below.
Result	:	Indicates analysis error caused by the sample, such as "SAMPLE NOT ASP ERROR", "LOW BLOOD VOLUME" or "LOW COUNT ERROR".

When pressing the [ERROR] key, the Analysis Error window as shown in Figure 4-9 will appear.

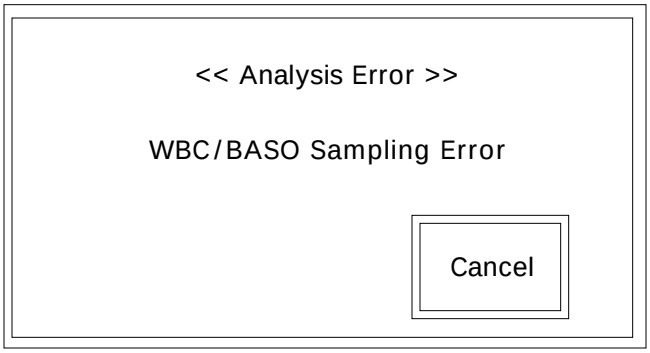


Figure 4-9: Analysis Error Window

Press the [Cancel] key to close the Analysis Error window.

3) Sample No.

The sample No. is displayed below the screen title. Sample numbers can consist of up to 13 digits, including hyphens. The following 3 types of indications appear in front of the number.

ID	:	Indicates that the number was read by ID bar code reader. If a number cannot be read by the bar code reader, "ID" is backlit in red.
C (backlit in green)	:	Indicates sample analyzed in the Capillary mode.
P (backlit in green)	:	Indicates sample analyzed in the Closed mode or Manual CP mode.

4) Date and Time

Date and time that the analysis results were received.

5) R: Rack No. – Tube Position Number

Rack No. and the tube position No. of the sample which was analyzed in Auto mode. "R:0000-00" is displayed for the sample analyzed in other modes.

6) DIFF Scattergram

Two-dimensional display of DIFF scattergram, according to the DIFF Channel data by flow cytometry using a semi-conductor laser. The horizontal and vertical axes are marked with scales consisting of 5 equal divisions. Refer to *Chapter 10, Section 6: WBC Scattergrams.*

7) WBC/BASO Scattergram

Two-dimensional display of WBC/BASO scattergram, according to the BASO Channel data by flow cytometry using a semi-conductor laser. The horizontal and vertical axes are marked with scales consisting of 5 equal divisions. Refer to *Chapter 10, Section 6: WBC Scattergrams.*

8) RBC Particle Size Distribution

Relative height curve showing RBC distribution.

9) PLT Particle Size Distribution

Relative height curve showing PLT distribution.

10) Analysis Data

A total of 23 parameters are displayed. The following indications may accompany the parameters. The indications appear after the data:

① ! (backlit in red):
Indicates that the data is outside the Critical Limits.
② * (backlit in red):
Indicates that the data is outside the Linearity Limits.
③ +, – (backlit in red):
Indicates that the data is outside the Sampler Stop Limits.
④ * (backlit in yellow):
Indicates that the data is unreliable because of an abnormality detected in the sample.
⑤ +, – (backlit in yellow):
Indicates that the data is outside the Mark Limits.

NOTE: The above indications are listed on the priority basis.

When an abnormality occurs in analysis data due to analysis error or some other causes, the following indications are displayed concerning the abnormal data.

① Analysis not possible – indicated by "----":
Indicates that analysis cannot be performed because identification of cell population or automatic discrimination is not possible.

② Out of display range – indicated by "++++":
Indicates that the numerical count exceeds the display range. (See *Chapter 1, "Instrument Specifications"* for the display range.)

③ Unreliable data – indicated by "****" or "*":
Indicates that the data may be unreliable because of an abnormality detected in the sample. (However, such data is displayed for reference in stored data graphic displays.)

④ Analysis error:
- Data obtained – indicated by "****":
Indicates that the data is unreliable because the Main Unit temperature or reagent temperature was outside the regulation range. (However, such data is displayed for reference in stored data graphic displays.)
- Data not obtained – indicated by "----":
Indicates that no data was obtained because an accurate analysis could not be performed (due to instrumental malfunction, such as Manometer malfunction etc.)

11) Interpretive (IP) Messages

WBC, RBC and PLT IP messages appear in the "WBC Flag", "RBC Flag" and "PLT Flag" boxes to the right of the screen. Each box can contain a maximum of 5 messages. If the total of abnormal plus suspect messages exceeds 5, suspect messages will get the priority, and a "▼" mark in yellow back-light will appear on the right of the 5th message.

5. DATA VALIDATION

Use this program to review and validate the data for report outputting it to the Printer or to the Host Computer. The data can be marked with "v" for auto output.

NOTE: "Auto Valid." program is used to automatically accept previously specified sample data to output to the peripheral devices. Refer to *Chapter 11* for the setting.

For data validation:

(1) Press the [Stored Data] keypad in the Root Menu. The List Display with second menu keys will appear.

(2) Use [↑], [↓], [Prev], and [Next] keys to move the cursor to specify the data to be reviewed. Press the [Graphic] keypad to display the graphic display screen for review, if needed.

(3) Press [Valid.] key. A "v" (validated) mark will appear on the left of the data in the List Display.

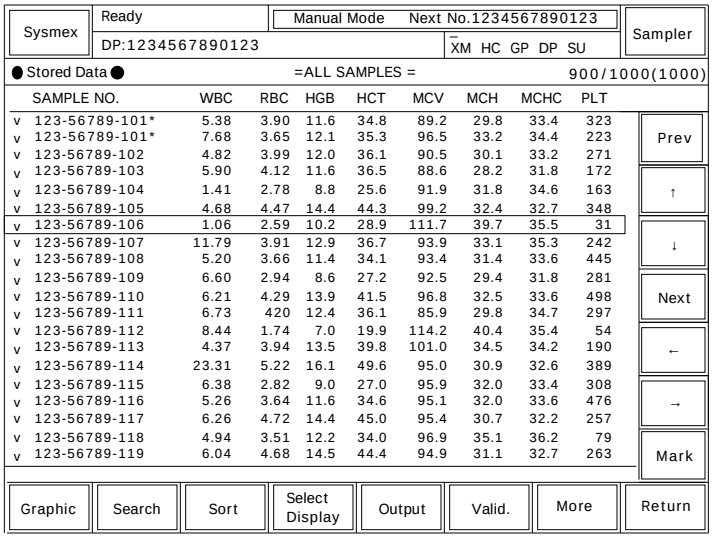


Figure 4-10: Data Validation Screen

NOTE: The "'v" mark is not displayed on Graphic Display.

6. MARK DATA

By pressing the [Mark] keypad in the List Display, the Mark Data screen as shown in Figure 4-11 will be displayed. In this program data is marked with a yellow square on the left edge of the screen for output and/or delete.

NOTE:
- Refer to *Section 11.2 : Marked Data (Output)* or *Section 12.2: Marked Data (Delete)*.
- The marks will be deleted automatically when the power turns OFF.

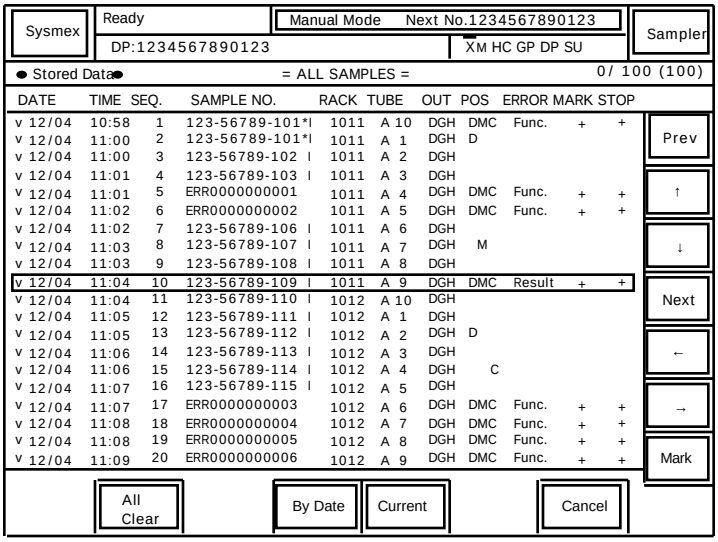


Figure 4-11: Mark Data Screen

Key Operation:

[All Clear] : Deletes existing yellow marks.
[By Date] : Marks with a yellow mark all data having the same date as the data the cursor is on. If same-date data were already marked with yellow marks, the marks are deleted.
[Current] : Marks the data the cursor is on with a yellow mark. If the data was already marked with a yellow mark, the mark is deleted.
[Cancel] : Returns to the List Display.

NOTE: If there is any marked data that has not been output or deleted, the message window "## marked data has been exist!!!" appears when the [Mark] key is pressed.
Delete the unprocessed mark(s), or delete or output the marked data.

7. SELECT DISPLAY

This program will allow the operator to select the type of samples to be displayed in the List Display program. This program can only select the samples that are stored in the memory.

To execute Select Display:

(1) Press the [Stored Data] keypad in the Root Menu. The List Display with second menu keys will appear.

(2) Press the [Select Display] keypad in the second menu. The Select Display submenu window shown in Figure 4-12 appears.

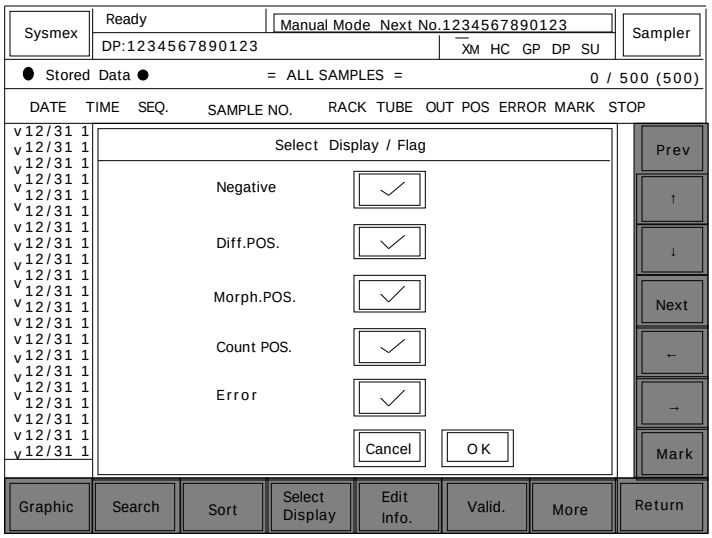


Figure 4-12: Select Display Submenus

(3) Press the desired keypad to specify the data that you want to appear on the List Display.
Refer to the following sections for the procedures.

NOTE: The List Display continues according to the selections made with this program until new settings are done. However, when the power is turned OFF, the list defaults to the original specifications of "All Samples".

7.1 Select By Flagging

This is for specifying the types of flagged data.

To specify flag types:

(1) Press the [By Flagging] keypad in the Select Display submenu window. The Select by Flagging window will appear, containing the current settings.

(2) Press the box key to the right of each item to specify for the type of flag. A "√" mark will appear in the box for selected items.
To delete the "√" mark (to exclude the item from display), press the key marked "√" again.

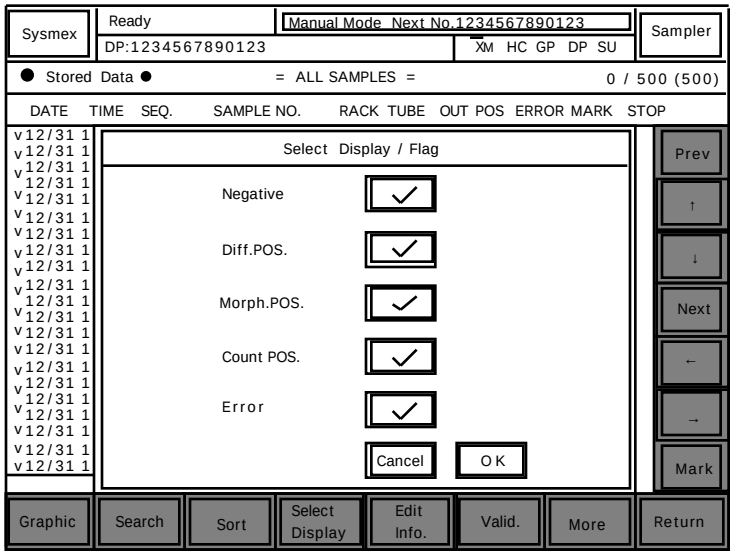


Figure 4-13: Select by Flagging Window

The flag types that can be specified are:

Negative	:	Analysis data with no abnormalities or analysis errors (excluding ID READ errors).
Diff. POS.	:	Data with an abnormality in WBC differential parameters.
Morph. POS.	:	Data with an abnormality in blood cell morphology.
Count POS.	:	Data with an abnormality in blood cell count.
Error	:	Data with analysis errors (excluding ID READ errors).

(3) Press [OK] to register the settings.
The data for which "√" (yes) was specified will be displayed in the List Display. The List Display screen name will contain the names of the specified flags as shown in the figure below. If yes is specified for all flags, the List Display title will change to "ALL SAMPLES".

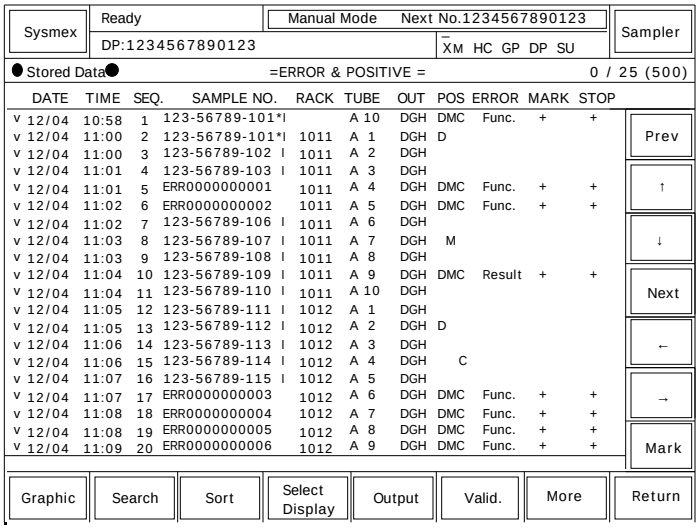


Figure 4-14: Flagging Data List Window

(4) Pressing [Cancel] key stops the program without changing the listing and returns to the List Display screen.

7.2 Select By Date

This is for specifying data of a particular date that are to appear in the List Display.

To specify the date:

(1) Press the [By Date] keypad in the Select Display Submenu window. The Date window will appear, containing a list of total No. of samples that are currently stored under each date (see Figure 4-15).

(2) Use the [↑] or [↓] keys to specify a date.

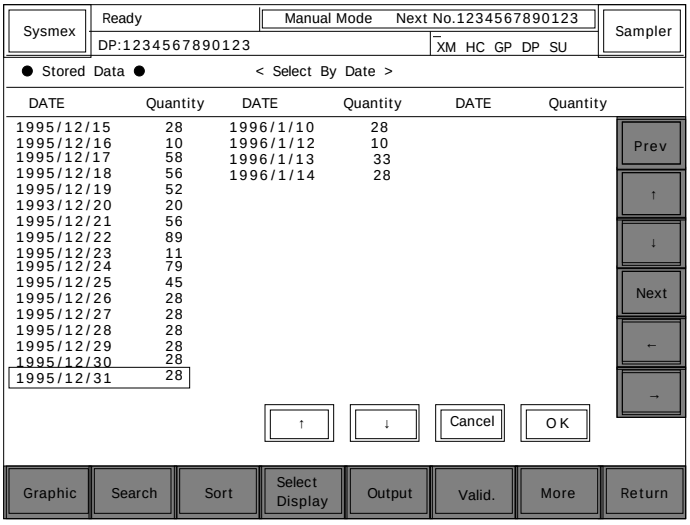


Figure 4-15: Select by Date Window

(3) Pressing [Cancel] key stops the program without changing the listing and returns to the List Display screen.

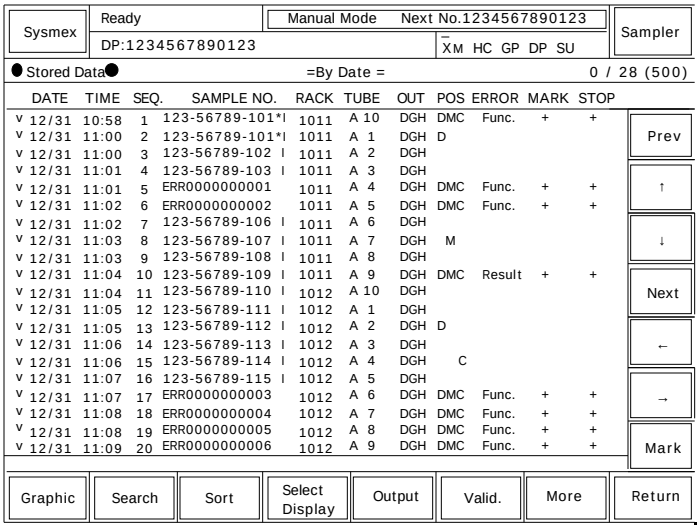


Figure 4-16: Select by Date List Window

(4) Press [OK] to set the date.
The data for the specified date will be displayed on the List Display.

7.3 Select By No Output

Use this program to specify the List Display to contain data that has not been output to a specified peripheral device(s).

To specify the output device:

(1) Press the [No Output] keypad in the Select Display Submenu window. The Select by No Output window will appear as shown in Figure 4-17.

(2) Press the box key on the right next to each item to specify the output condition. A "√" mark will be placed in the box for the selected item.

> **NOTE:** Two or more items cannot be selected at a time.

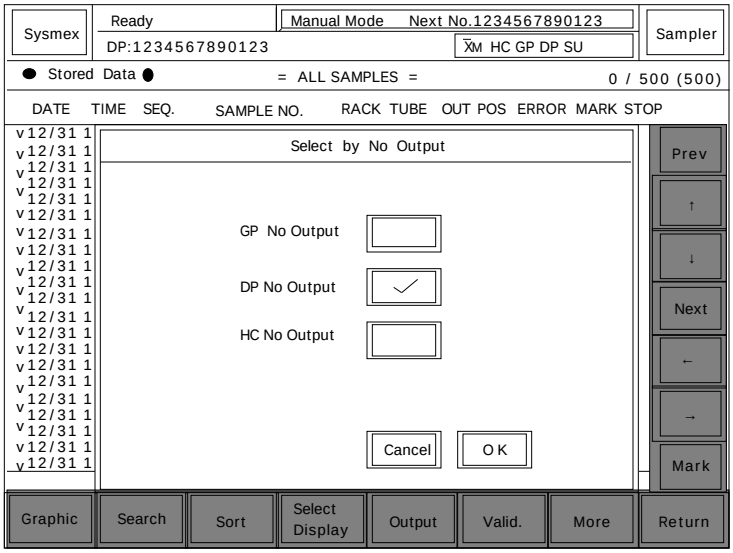


Figure 4-17: Select by No Output Window

(3) Press [OK] to set the specifications.
The data that has not been output to the specified peripheral device will be displayed on the List Display. The List Display screen name containing the selected item will appear.

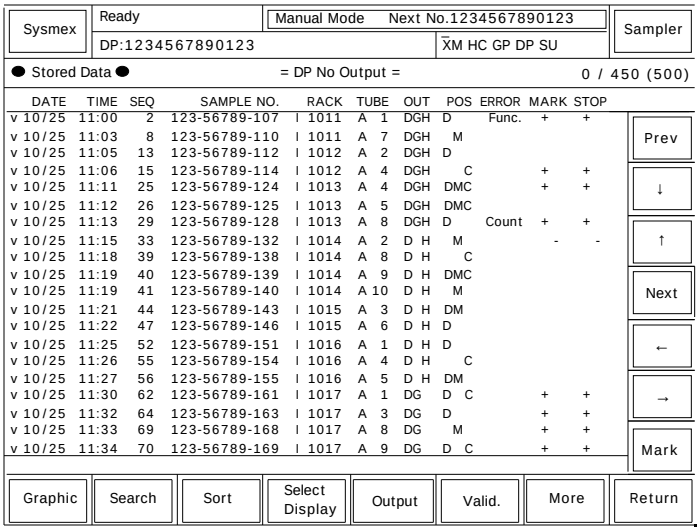


Figure 4-18: Example of No Output Data Listing
(Data that has not been output to DP)

(4) Pressing [Cancel] key stops the program without changing the listing and returns to the List Display screen.

7.4 QC Data

Use this program to display a list of QC analysis data (by L-J Control Method) stored in the memory. The list can contain up to 1000 samples.

To display a list of QC data:

(1) Press the [QC Data] keypad. A list of QC analysis data will be displayed as shown in Figure 4-19. The List Display screen name will change to "QC Data".

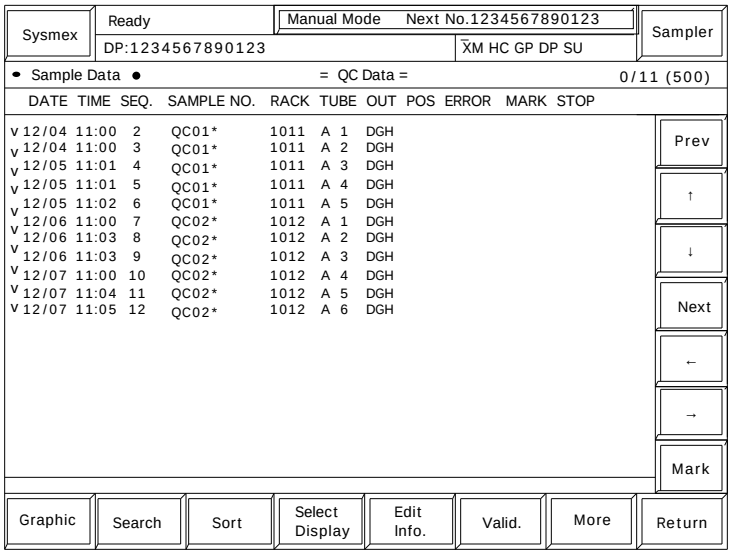

Sysmex
Ready
Manual Mode Next No.1234567890123
Sampler
DP:1234567890123
X̄M HC GP DP SU
• Sample Data •
= QC Data =
0/11 (500)
DATE TIME SEQ. SAMPLE NO. RACK TUBE OUT POS ERROR MARK STOP
v 12/04 11:00 2 QC01* 1011 A 1 DGH
v 12/04 11:00 3 QC01* 1011 A 2 DGH
v 12/05 11:01 4 QC01* 1011 A 3 DGH
v 12/05 11:01 5 QC01* 1011 A 4 DGH
v 12/05 11:02 6 QC01* 1011 A 5 DGH
v 12/06 11:00 7 QC02* 1012 A 1 DGH
v 12/06 11:03 8 QC02* 1012 A 2 DGH
v 12/06 11:03 9 QC02* 1012 A 3 DGH
v 12/07 11:00 10 QC02* 1012 A 4 DGH
v 12/07 11:04 11 QC02* 1012 A 5 DGH
v 12/07 11:05 12 QC02* 1012 A 6 DGH
Prev
↑
↓
Next
←
→
Mark
Graphic
Search
Sort
Select Display
Edit Info.
Valid.
More
Return

Figure 4-19: QC Data List Window

7.5 All Samples

Use this program to specify the List Display to contain all of the stored data.

To display All Samples:

(1) Press the [All Data] keypad. All of the currently stored data will appear as shown in Figure 4-20. The List Display screen name will change to "ALL SAMPLES".

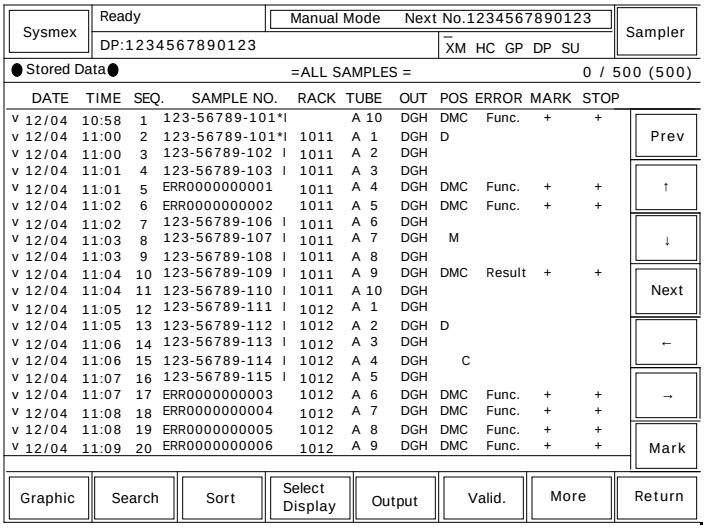


Figure 4-20: All Samples List Screen

7.6 Read FD

Use this program to download stored sample data from a floppy disk.

NOTE: Sample data from a floppy disk cannot be written onto the hard disk.

To download data from FD:

(1) Press the [FD Data] keypad in the Select Display submenu window. The FD Read window will appear.

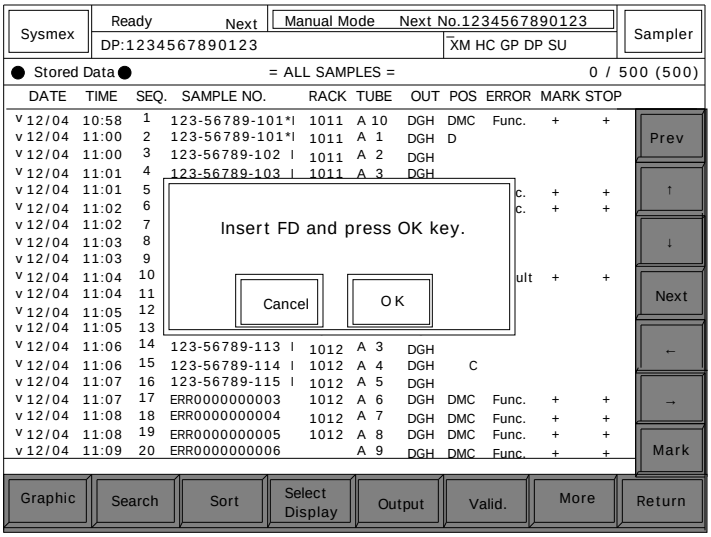


Figure 4-21: FD Read Window

(2) Insert the disk into the drive and press [OK]. The data will be read in from the disk. "Reading ... " will appear in the window while data is being read in. Press [Stop] to stop reading.

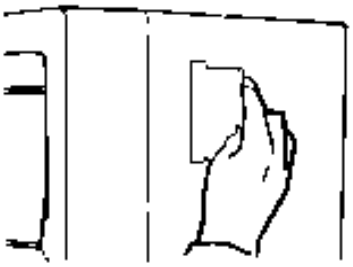


Figure 4-22: Insert Disk

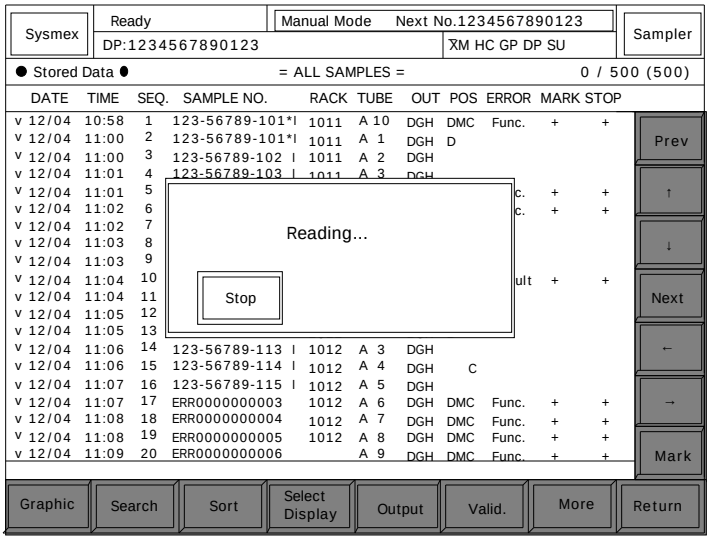


Figure 4-23: FD Reading Message Window

(3) The data read from the disk will be displayed in a list. This data can be processed in the same way as stored sample data.

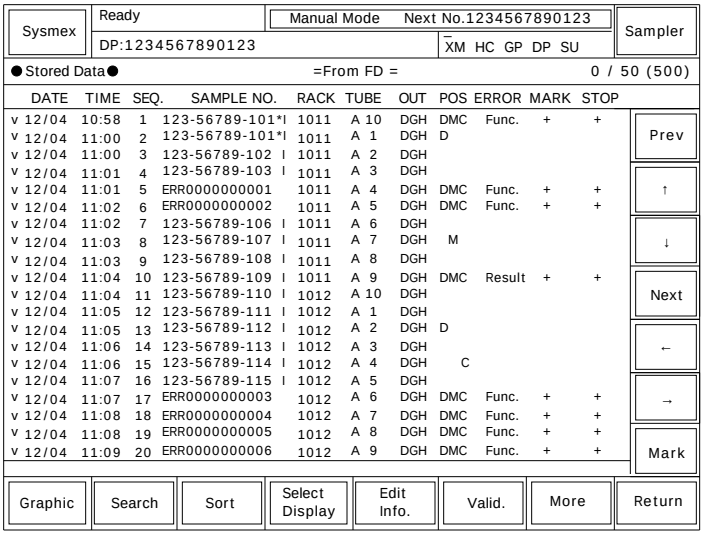


Figure 4-24: FD Data List Screen

If data cannot be read, the message "FD read Error. Insert FD and press OK key" will appear in a window. Insert the correct disk and press [OK]. To cancel the process and exit the program, press [Cancel].

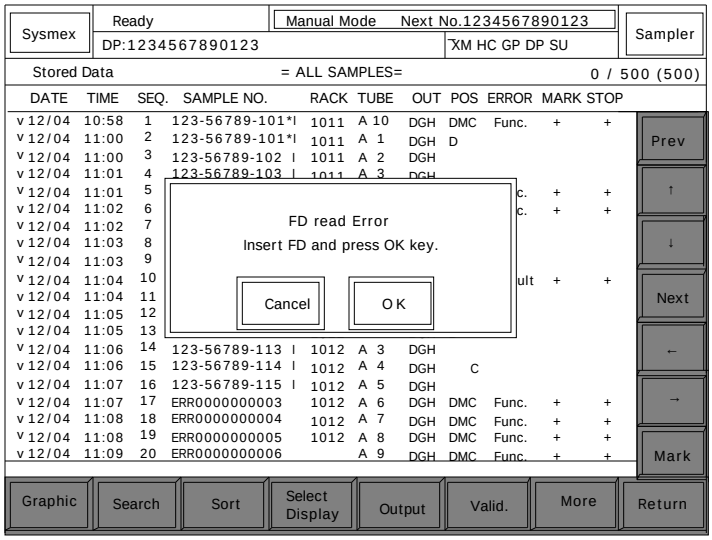


Figure 4-25: FD Read Error Message Window

NOTE: Do not remove the floppy disk before you have exited the FD Read program. If the floppy disk was removed before exiting FD Read program, the list will be automatically changed to List Display of All Samples.

8. SEARCH STORED DATA

This program will allow the operator to specify a data and to display the List Display with the data at the top/bottom of the screen.

To execute search program:

(1) Press the [Stored Data] keypad in the root menu. The List Display with second menu keys will appear.

(2) Move the cursor to a data before searching data with the same analysis date.

(3) Press the [Search] keypad in the second menus. The Search window as shown in Figure 4-26 appears.

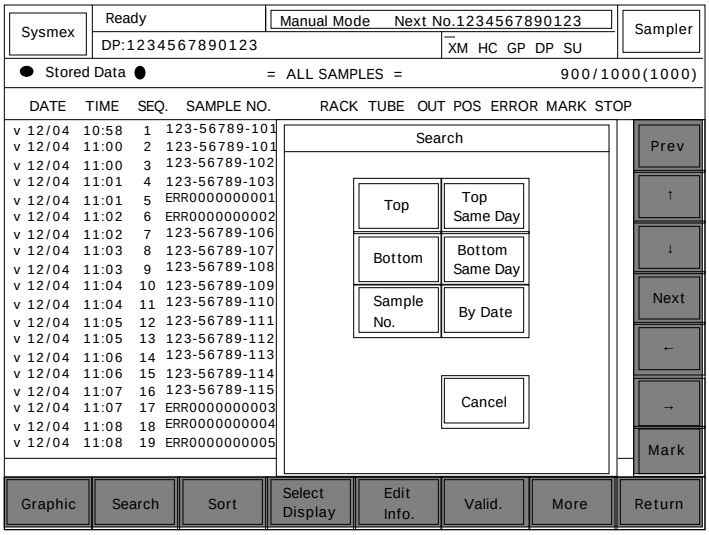


Figure 4-26: Search Window

(4) Press the desired keypad to specify the data and the List Display.
Refer to the following sections for the procedures.

8.1 Top/Bottom

(1) Press [Top] key in Search window to display the top of the list at the top of the List Display.
Press [Bottom] key to display the end of the list at the bottom of the List Display.

(2) Pressing [Cancel] key cancels the program and returns to the List Display screen.

8.2 By Sample No.

Use this program to specify data of a particular sample No. that you want to appear at the top of the List Display.

NOTE: This program searches and displays the specified data at the top of the List Display. It does not prepare a list consisting of only the data specified.

To execute the search by Sample No.:

(1) Press [Sample No.] key in Search window. The numeric entry window is displayed as shown in Figure 4-27. Input the sample No. and press the [ENTER] key.

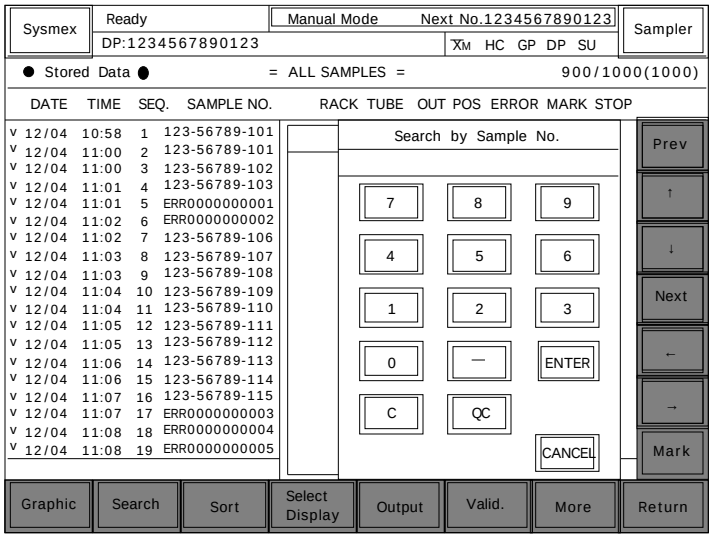


Figure 4-27: Sample No. Input Screen

(2) Data with the specified sample No. will be searched, and the specified data will be displayed at the top of the List Display.

(3) If there was no specified data, the message "Specified data is not found." will be displayed as shown in Figure 4-28. Press the [OK] key to stop the program and return to the List Display screen.

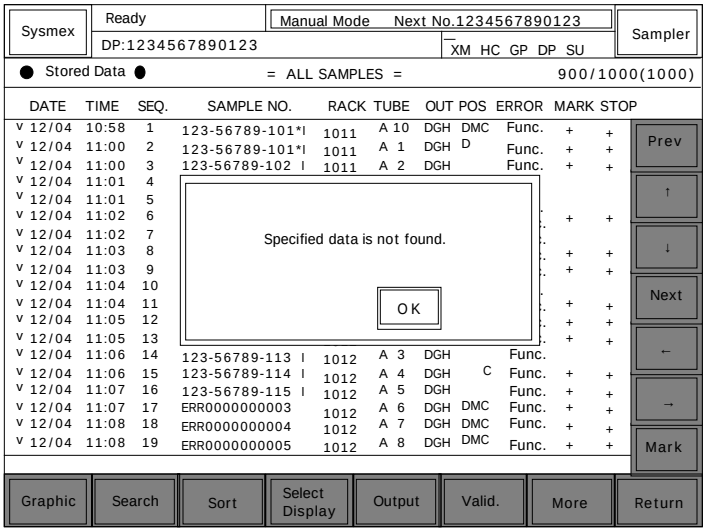


Figure 4-28: Data Was Not Found

8.3 Same Day

Use this program to specify data of a particular date with the cursor that you want to appear at the top or the bottom of the List Display.

NOTE: This program searches and displays the cursor at the data which was obtained first or the last on the specified date. It does not prepare a list consisting of only the data specified.

To execute the search by Same Day:

(1) Press [Top Same Day] key in Search window. The analysis data found at the first for the specified date will be displayed on the list.
Press [Bottom Same Day] key. The analysis data which was found at the last for the specified date will be displayed on the list.

(2) Pressing [Cancel] key cancels the program and returns to the List Display screen.

8.4 By Date

Use this program to specify data of a particular date that you want to appear at the top of the List Display.

NOTE: This program searches and displays the specified data at the top of the List Display. It does not prepare a list consisting of only the data specified.
Refer to *Section 7.2: Select By Date (Select Display)* in this chapter to make a list consisting of the data with specified date.

To specify the date:

(1) Press the [By Date] keypad in Search window. The Date window will appear, containing a list of total No. of samples that are currently stored under each date (see Figure 4-29).

(2) Use the [↑] or [↓] keys to specify a date.

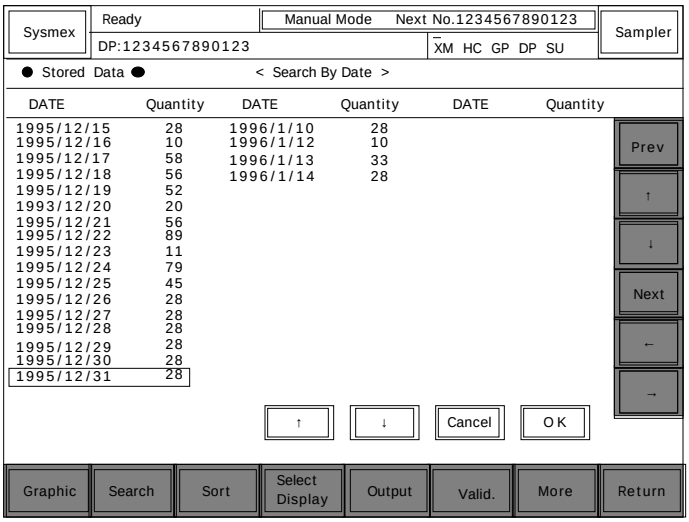


Figure 4-29: Search by Date Window

(3) Press [OK] to select the date.
The data for the specified date will appear at the top of the List Display.

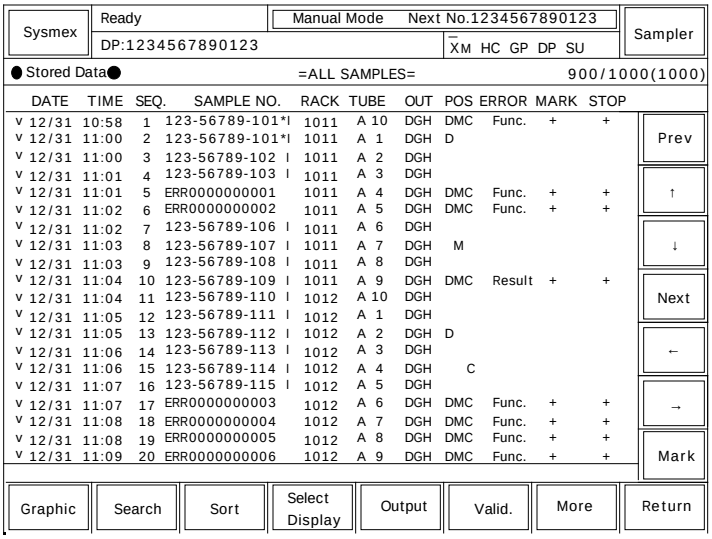


Figure 4-30: Search by Date List Window

(4) Pressing [Cancel] key stops the program without changing the listing and returns to the List Display screen.

9. SORT STORED DATA

Use this program to arrange the List Display of data obtained on the same date in chronological order of sample analysis or in order of the Sample ID No.

NOTE: This program sorts the List Display which is selected by Select Display program. Select other List Displays if necessary (refer to *Section 7: Select Display*).

9.1 Sequence Order

This program arranges the data obtained on the same date in chronological order and displays the List Display.

To specify Sequence Order:

(1) Press the [Stored Data] keypad in the Root Menu. The List Display with second menu keys will appear.

(2) Press the [Sort] keypad in the second menus. The Sort screen will appear (Figure 4-31).

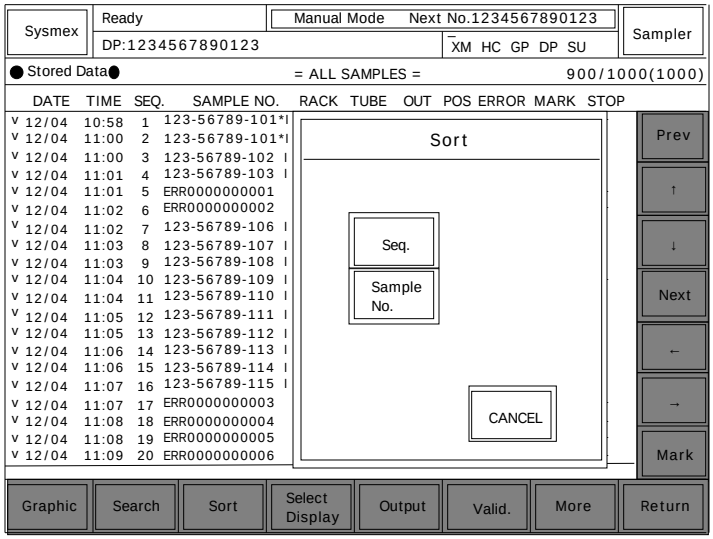


Figure 4-31: Sort Screen

(3) Press [Seq.] key. The data obtained on the same date will be arranged in the chronological order of analysis and listed as shown in Figure 4-32.

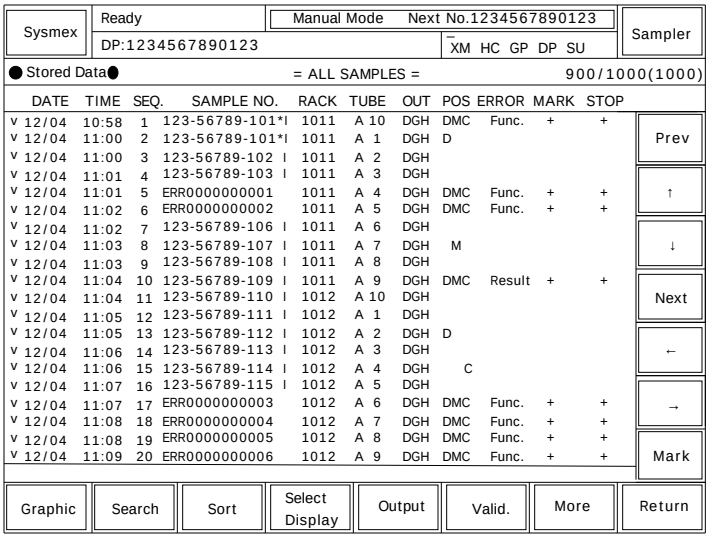


Figure 4-32: Sequence Order List Screen

9.2 Sample No. Order

This program arranges the data obtained on the same date in the order of the Sample ID No. and displays the List Display

To specify Sequence Order:

(1) Press the [Stored Data] keypad in the Root Menu. The List Display with second menu keys will appear.

(2) Press the [Sort] keypad in the second menus. The Sort screen will appear.

(3) Press [Sample No.] key. The data obtained on the same date will be arranged in the order of the Sample ID No. and listed as shown in Figure 4-33.

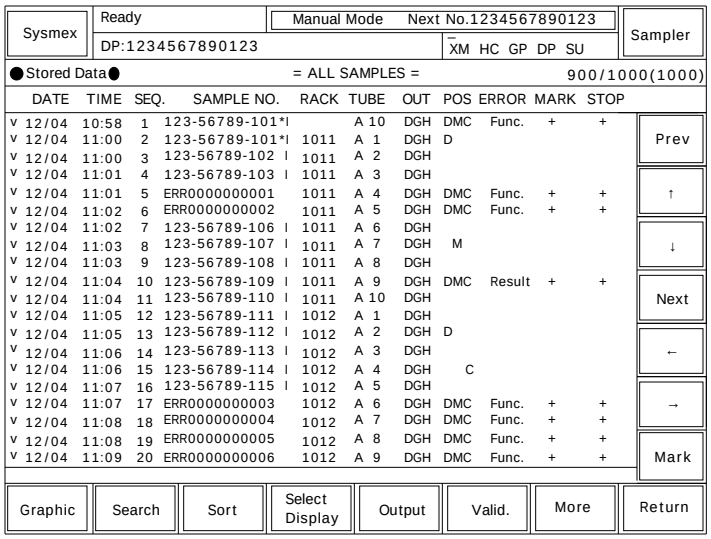


Figure 4-33: Sample No. Order List Screen

NOTE: Sample ID No. consists of digits, hyphens, and letters in the case of ID READ Error. When the Sample ID No. contains letters, they are listed according to the ASCII code order. The more characters a Sample ID No. contains, the lower down on the list the sample is found.
Sample ID Nos. are ordered according to this priority rule:
– < ... < 0 < ... < 9 < ... < A < ... < Z

NOTE: After the instrument is powered OFF, the List Display will be automatically arranged in chronological order.

10. EDIT SAMPLE INFORMATION

Use this program to change sample information of the analysis data stored in the memory.

To execute Edit Info.:

(1) Press the [Stored Data] keypad in the root menu. The List Display with second menu keys will appear.

(2) Use [↑], [↓], [Prev], and [Next] keys to move the cursor to specify the sample whose sample information is to be changed.

(3) Press [More] key in the second menus, and press the [Edit Info.] keypad. The Edit Sample Information window as shown below appears.

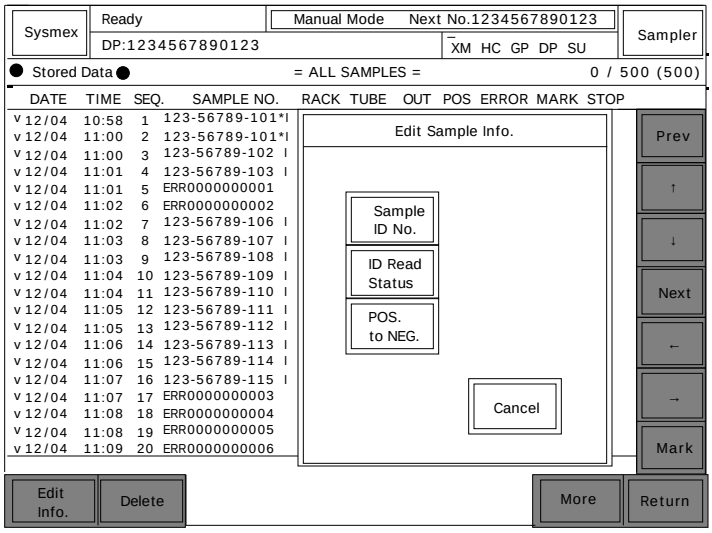


Figure 4-34: Edit Sample Info. Window

(4) Press the appropriate keypad to edit the desired sample information. Refer to the following sections for the procedures.

10.1 Sample No.

Use this program to change Sample Nos.

To execute edit sample ID No.:

(1) Press [Sample ID No.] key in the Edit Sample Info. window. The numeric entry window as shown in Figure 4-35 is displayed.

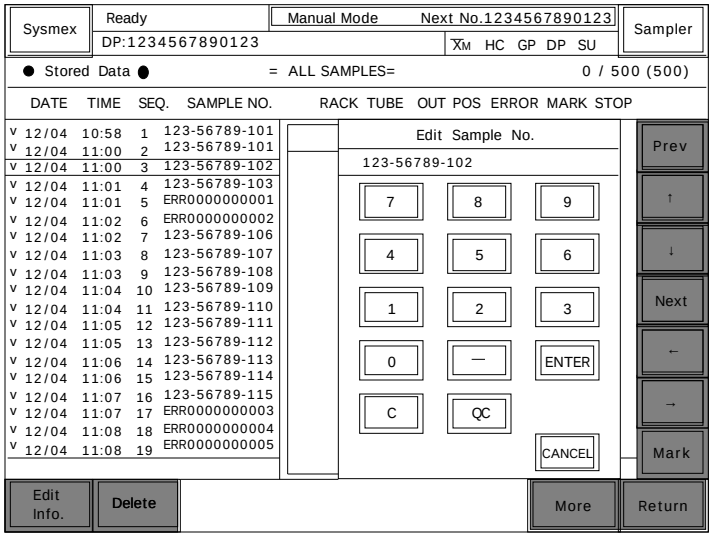


Figure 4-35: Sample No. Input Screen

(2) Input the new sample No. The new number is displayed on the bar above the numeric keys.

(3) Pressing [ENTER] alters the sample No. and returns to the List Display. Pressing [QUIT] stops the program without changing the sample No., and returns to the List Display.

NOTE:
- When [ENTER] is pressed, the new number is checked to see that it complies with the Sample Number Input Rules. If it does not, the alarm will beep and the number must be entered again.
- When the list is sorted in Sample ID No. order, the sample will automatically be moved according to its new sample No.

10.2 ID Read Status

Use this program to change the ID Read notation of a sample that was read by the ID reader or entered by the operator.

(1) Press [ID Read Status] key in the Edit Sample Info. window. "I" is placed on the right of the ID number. If the sample already has an "I" next to the ID number, it is removed. The display returns to the List Display.

(2) Press [Cancel] to stop the program without changing the ID Read Status, and to return to the List Display.

10.3 POS to NEG

Use this program to change the POSITIVE status of a stored sample data to the NEGATIVE.

NOTE: Data judged NEGATIVE cannot be changed to POSITIVE.

(1) Press [POS. to NEG.] key in the Edit Info. window. The confirmation message window appears.

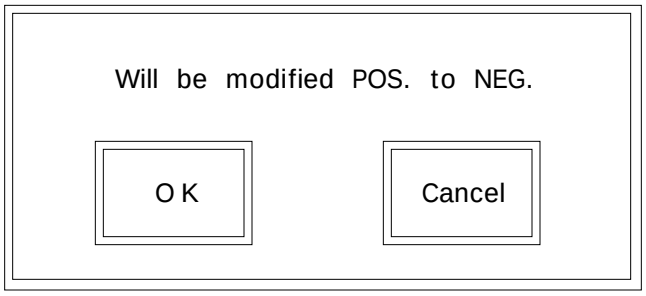


Figure 4-36: POS to NEG Confirmation Window

CAUTION: POS data changed to NEG cannot be changed back to POS. Carefully think about your action before pressing [OK].

(2) Press [Cancel] to stop the program without changing the status, and to return to the List Display.

(3) Press [OK] to execute POS to NEG and return to the List Display. "Mod" is displayed in POS column in List Display (P1). The flag item numbers in List Display (P6) disappear. On the graphic display, "Modified" is displayed under the NEGATIVE status indicator of the sample.

11. OUTPUT STORED DATA

With this program, you can output specified stored data from the List Display. If you select this menu, the "Output" submenu appears, enabling you to choose "Current Data", "Marked Data", "All Data" and "Cancel Output".

NOTE: This program outputs the data from the List Display which is selected by Select Display program. Select other List Displays if necessary (refer to *Section 7: Select Display*).

To output stored data:

(1) Press the [Stored Data] keypad in the Root Menu. The List Display with second menu keys will appear.

(2) When executing output of current data, move the cursor to specify the data to be output.

(3) Press the [More] keypad in the second menus, and press [Output] key in the second menus. The Select Sample window as shown in Figure 4-37 appears.

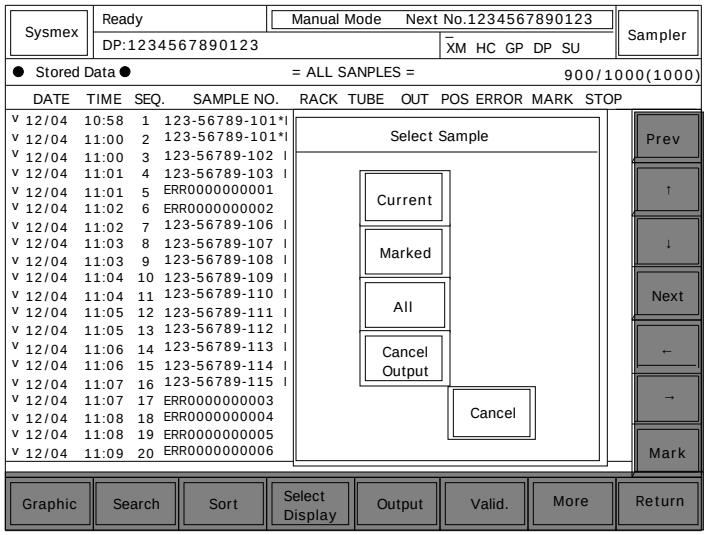


Figure 4-37: Select Sample Window

NOTE: When the [Output] key is pressed while a graphic display appears on the LCD, Select Device window as shown in Figure 4-38 will appear. Only the displayed sample will be output.

(4) Press the desired keypad to select the data for output. The Select Device window as shown in Figure 4-38 will appear to specify a peripheral device for the selected data.

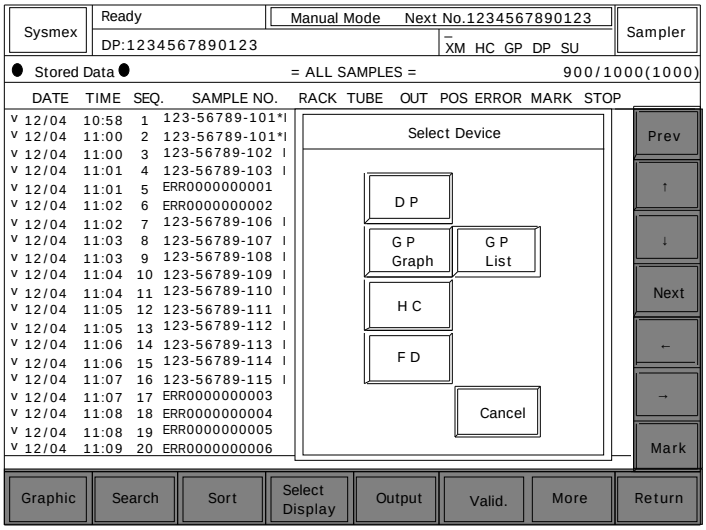


Figure 4-38: Select Device Window

(5) Select an appropriate device by pressing DP (Data Printer), GP Graph (Graphic Printer), GP List (Graphic Printer) or HC (Host Computer) keypad. The output to the selected device will start.

NOTE: Refer to *Section 11.5: Backup (FD)* to output the data to a floppy disk.

Data output is executed as follows:

DP : The specified data is printed in a columnar format onto a print ticket.
GP Graph : The specified sample's graphic display screen is printed.
GP List : The specified data is printed in a line print format.
HC : The specified data is transmitted to the host computer.

(6) Refer to the following sections for the procedures.

11.1 Current Data

This program specifies the data the cursor is on for output to one of the Printers or to the Host Computer.

To output current data:

(1) Press [Stored Data] to display the List Display.

(2) Use [↑], [↓], [Prev] and [Next] keys to move the cursor to specify the data to be output.

(3) Press [Output] to display the Select Sample window.

(4) Press [Current] key. The Select Device window will appear.

(5) Select a device by pressing [DP], [GP Graph], [GP List] or [HC] keypad. The output to the selected device will start.
(Press [Quit] to stop the program without outputting the data, and to return to the List Display.)

(6) To cancel the data output after it has begun, press [Output] and then [Cancel Output] key in the Select Sample window.
Refer to *Section 11.4: Cancel (Output).*

NOTE:	Wait until printing is complete before specifying another output for printing.

11.2 Marked Data

This program specifies the marked data for output to one of the Printers or to the Host Computer.

To output marked data:

(1) Press the [Stored Data] keypad in the Root Menu. The List Display with second menu keys will appear.

(2) Press the [Mark] keypad to the right of List Display. Mark the data which will be output, if necessary. Refer to *Section 6: Mark Data* for the procedure.

(3) Press the [More] keypad in the second menus, and press [Output] key in the altered second menus. The Select Sample window will appear.

(4) Press [Marked] key. The Select Device window will appear.

(5) Select a device by pressing [DP], [GP Graph], [GP List] or [HC] keypad. The output to the selected device will start.
(Press [Quit] to stop the program without outputting the data, and to return to the List Display.)

(6) To cancel the data output after it has begun, press [Output] and then [Cancel Output] key in the Select Sample window. Refer to *Section 11.4: Cancel (Output).*

NOTE:
- Wait until printing is complete before specifying another output for printing.
- The marks will be cleared after the instrument power is OFF.

11.3 All Data

All the stored data can be output to one of the Printers or to the Host Computer.

To output all data:

(1) Press [All] key in the Select Sample window. The Select Device window will appear.

(2) Select a device by pressing [DP], [GP Graph], [GP List] or [HC] keypad. The output to the selected device will start.
(Press [Quit] to stop the program without outputting the data, and to return to the List Display.)

(3) To cancel the data output after it has begun, press [Output] and then [Cancel Output] key in the Select Sample window. Refer to *Section 11.4: Cancel (Output).*

NOTE: Wait until printing is complete before specifying another output for printing.

11.4 Cancel Output

Use this program to cancel data output process after it has begun.

To execute cancellation:

(1) Press the [Stored Data] keypad in the Root Menu. The List Display with second menu keys will appear.

(2) Press the [Output] keypad in the second menus. The Select Sample window will appear.

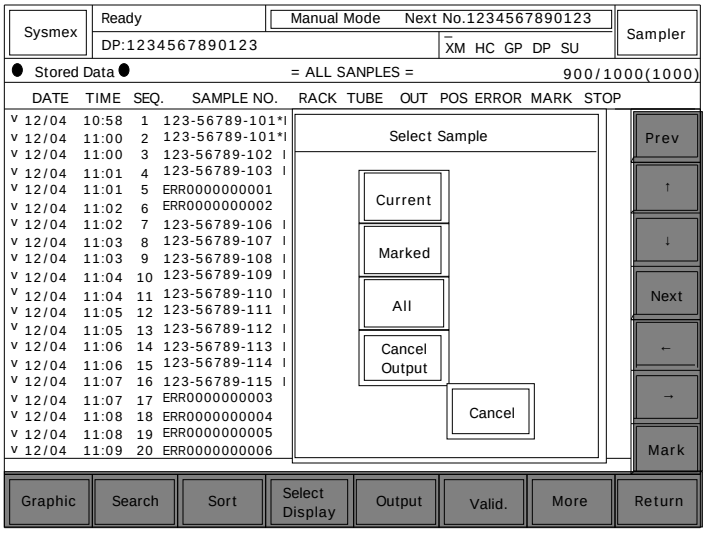


Figure 4-39: Select Sample Window

(3) Press [Cancel Output] key. The Select Device window will appear.

(4) Select a device by pressing [DP], [GP Graph], [GP List] or [HC] keypad. The output to the selected device will be canceled.
Press [Cancel] to quit the cancellation and to return to the List Display. The output being executed is continued.

11.5 Backup (FD)

Use this program to backup analysis data stored in the memory to a floppy disk.

NOTE:
- The floppy disk should be pre-formatted in MS-DOS 1.44 MB format using "Mainte." - "Format FD" program. Refer to *Chapter 5, Section 10: Format FD* for the procedure. An unused, commercially pre-formatted MS-DOS 1.44 MB floppy disk also can be used.
- If there is too much data to fit in one disk, select unneeded data and delete it or use more than one disk for backup.

To output data to floppy disk:

(1) Press the [Stored Data] keypad in the Root Menu. The List Display with second menu keys will appear.

(2) Press [Output] key in the a second menus. The Select Sample window will appear.

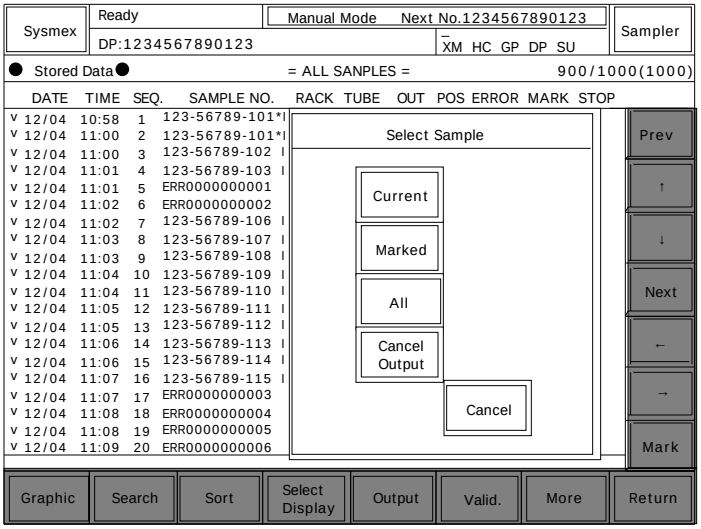


Figure 4-40: Select Sample Window

(3) Specify the data for backup in a floppy disk by pressing [Current], [Marked] or [All] keypad. (Refer to *Section 11.1: Current Data, 11.2: Marked Data* or *11.3: All Data* in this Chapter for specifying the data.) The Select Device window will appear as shown in Figure 4-41.

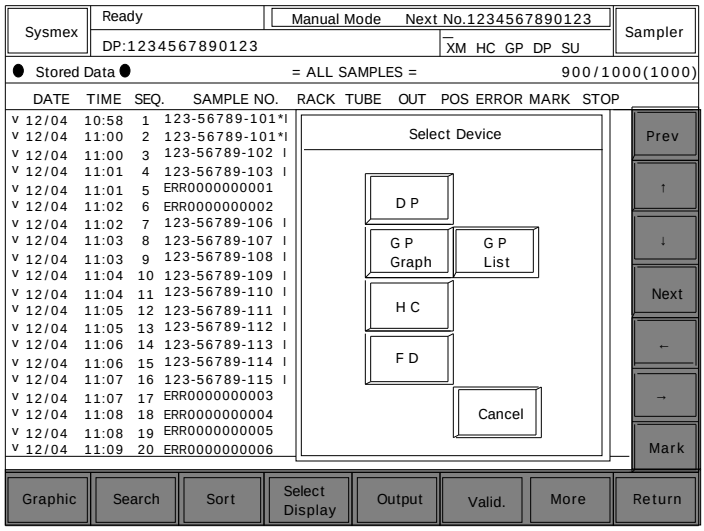


Figure 4-41: Select Device Window

(4) Press [FD] key. The Backup Confirmation message will be displayed as shown in Figure 4-42.

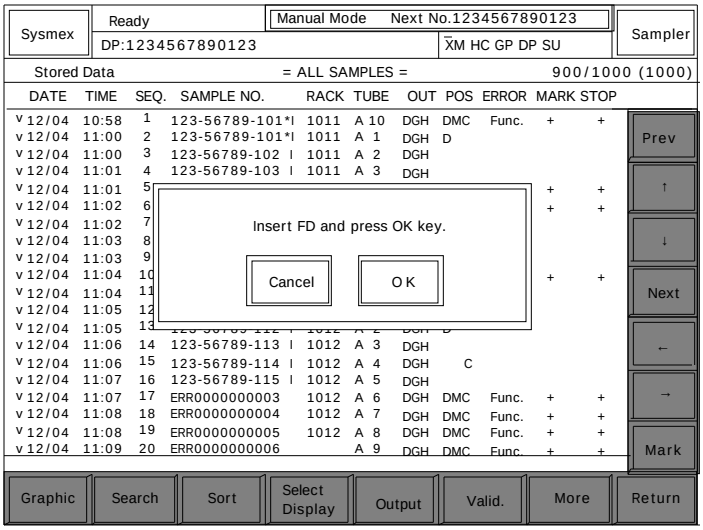


Figure 4-42: Backup Confirmation Message Window

(5) To cancel processing and to exit the program, press [Cancel].
To start the backup, insert the disk into the drive and press [OK]. The specified data will be written onto the floppy disk. While writing is in progress, the message "Writing..." will appear (see Figure 4-43).

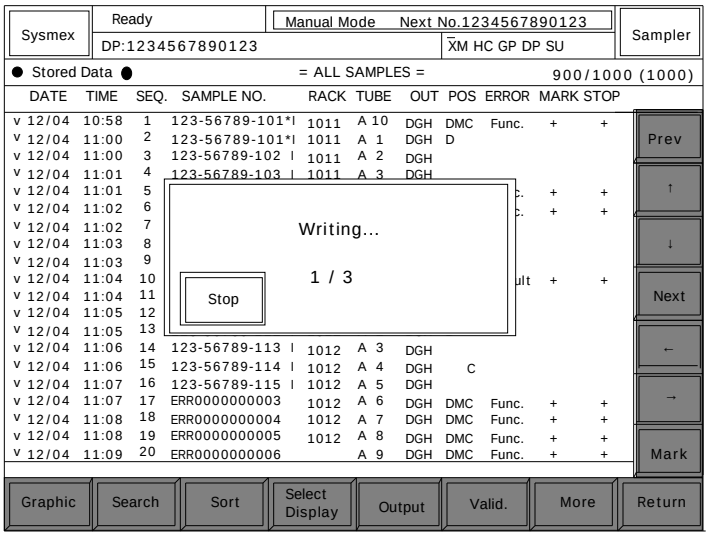


Figure 4-43: FD Writing Message Window

(6) Press [Stop] to stop writing and exit the program.

(7) If the specified data cannot be written onto the floppy disk, the message "FD write Error! Insert FD and press OK key" will appear in the FD write window.

NOTE: When the floppy disk becomes full, this same error message is displayed. Insert a new pre-formatted floppy disk.

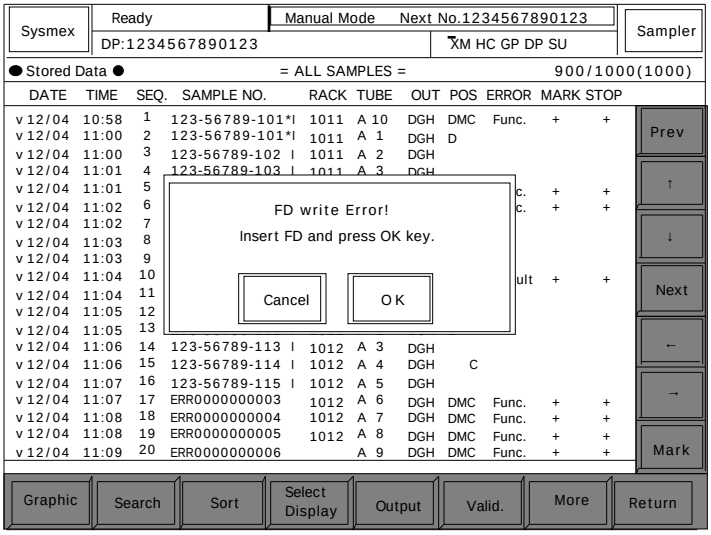


Figure 4-44: FD Write Error Message Window

(8) Insert the correct type of floppy disk into the drive, and press [OK] key. Pressing [Cancel] cancels writing process and exits the program.

(9) When the data has been written onto the floppy disk, the program ends.

12. DELETE

With this program, you can delete specified stored data in the List Display. If you select this menu, the "Delete" submenu appears, enabling you to choose "Current Data", "Marked Data" and "All Data".

NOTE: This program deletes the data in the List Display which is selected by Select Display program. Select other List Displays if necessary (refer to *Section 7: Select Display*).

To delete stored data:

(1) Press the [Stored Data] keypad in the Root Menu. List Display with second menu keys will appear.

(2) Move the cursor to specify the data to be deleted for executing deletion of current data.

(3) Press the [More] keypad in the Second menus, and press [Delete] key in the altered Second menu.
The Select Sample window appears as shown in Figure 4-45.

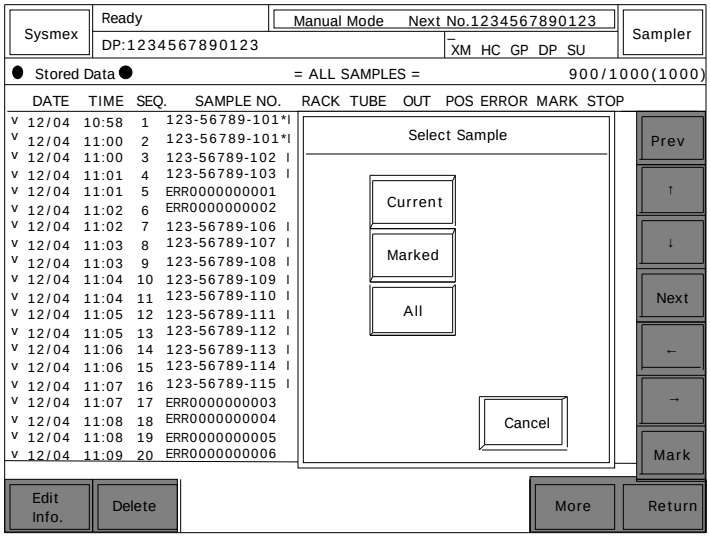


Figure 4-45: Select Sample Window

(4) Press the desired keypad to specify the data to be deleted.

(5) Press [OK] to delete the data.
Refer to the following sections for the procedure.

12.1 Current Data

In this program, the data that is deleted is specified by using the cursor.

To delete current data:

(1) Press the [Stored Data] to display the List Display.

(2) Use [↑], [↓], [Prev], and [Next] keys to move the cursor and select the data to be deleted.

(3) Press [Delete] key to display the Select Sample window.

(4) Press [Current] key. The Delete Confirmation window will appear as shown in Figure 4-46.

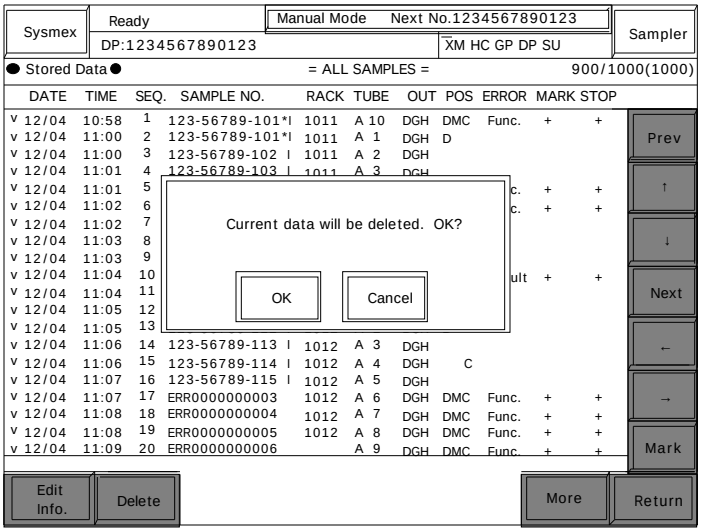


Figure 4-46: Delete Confirmation Window

(5) Press [OK] to delete the data with the cursor on it. Program deletes the data and exits. The screen returns to List Display.
Press [Cancel] to end the program without deleting the data.

NOTE: The data cannot be restored once deleted.

12.2 Marked Data

This program specifies marked data for deletion.

To delete marked data:

(1) Press the [Stored Data] to display the List Display.

(2) Press the [Mark] keypad to mark the data which will be deleted, if necessary. Refer to *Section 6: Mark Data* for the procedure.

(3) Press [Delete] key to display the Select Sample window.

(4) Press [Marked] key. The Delete Confirmation window will appear.

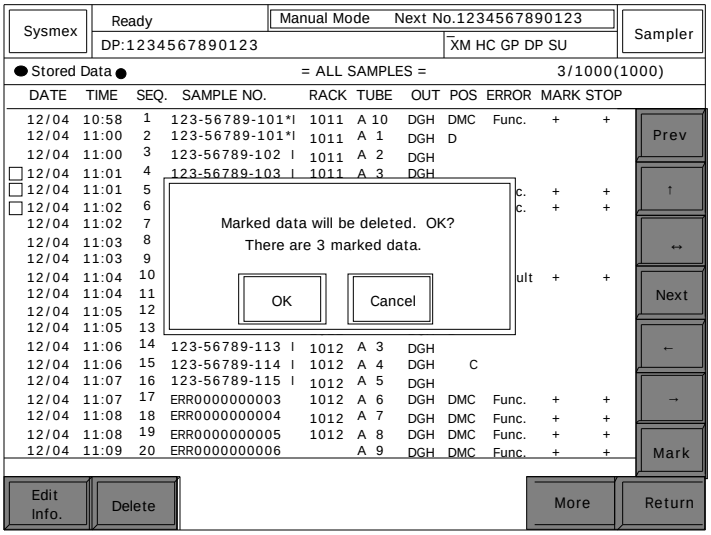


Figure 4-47: Delete Confirmation Window

(5) Press [OK] to delete the marked data. Program deletes the data and exits. The screen returns to List Display.
Press [Cancel] to end the program without deleting the data.

NOTE: The data cannot be restored once deleted.

12.3 All Data

Use this program to delete all the stored sample data.

To delete all data:

(1) Press the [Stored Data] keypad to display the List Display.

(2) Press [Delete] key to display the Select Sample window.

(3) Press [All] key. The Delete Confirmation window will appear.

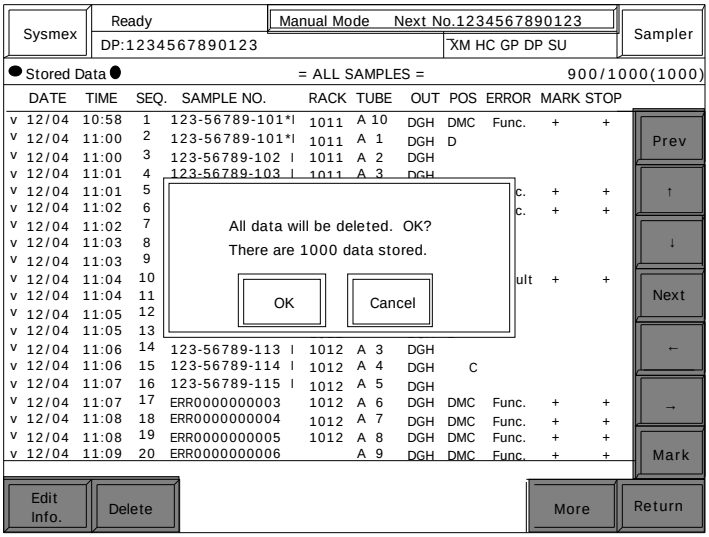


Figure 4-48: Delete Confirmation Window

(4) Press [OK] to delete all stored sample data. Program ends.
Press [Cancel] to end the program without deleting the data.

NOTE: The data cannot be restored once deleted.

13. AUTO OUTPUT

The SF-3000 automatically prints out analysis data to a Data Printer and Graphic Printer, and automatically transmits analysis data to the Host Computer. Data is output according to preset conditions.

The Auto Output function outputs only data that is validated for reporting and has not previously been output. Output status of stored samples is indicated in the OUT column on the analysis data lists. D (DP), G (GP), and H (HOST) in the OUT column indicate that data has not yet been output to the Data Printer, Graphic Printer and Host Computer, respectively. To output a data that has been output by Auto Output, use [Output] program.

Data is output in chronological sequence, starting with the oldest data (first-in, first-out). In the case of Data Printer output, it is also possible to output only the most recent data (the last sample analyzed).

To set data output conditions and specify samples to be output, use "Output Condition" and "Output Mode" of the "Settings" program.

Data output condition setting consists of selecting "FIFO" or "STOP" for each output mode. Selecting "FIFO" will output data in first-in, first-out order except in the case of the Data Printer, for which "LAST" can also be specified. To stop an auto output mode, select STOP.

Output conditions:

DP	:	STOP, FIFO, LAST
GP	:	STOP, FIFO
HC	:	STOP, FIFO

The type of sample that will be output is individually specified for each output mode. Only the specified samples are output.

Types of stored samples that can be specified for output:

Negative	:	Analysis data without abnormality or analysis errors (excluding ID READ errors).
Diff. POS.	:	Data with abnormality in WBC differential parameters.
Morph. POS.	:	Data on samples with abnormal cell morphology.
Count POS.	:	Data with abnormality in blood cell count.
Error	:	Data with analysis errors (excluding ID READ errors).
QC Data	:	QC data that has been performed.

(Refer to *Chapter 11. System Setup* for details.)

CHAPTER 5 MAINTENANCE & SUPPLIES

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1. INTRODUCTION

To keep the SF-3000 in optimal operating condition, periodic maintenance is required. Use the schedule below as a guide, and record your work on the maintenance check list found in *Section 2* of this chapter.

- **DAILY:**
  Clean detector chambers and manometers (shutdown sequence).
  Remove fluid from Pneumatic Unit trap chamber.

- **WEEKLY:**
  Clean SRV (sample rotor valve) tray.
  Execute WBC detector cleaning sequence.

- **MONTHLY:**
  Clean orifice.
  Execute waste chamber cleaning sequence.
  Clean sample rotor valve (SRV)

- **YEARLY:**
  Visible inspection of laser unit

- **AS NEEDED:**
  Clean manual rinse mechanism.
  Execute RBC aperture clog removal sequence.
  Execute RBC detector cleaning sequence.
  Clean RBC detector aperture.
  Execute WBC flow cell air bubble removal sequence.
  Execute sheath flow reagent replacing sequence.
  Replace waste container (if used).

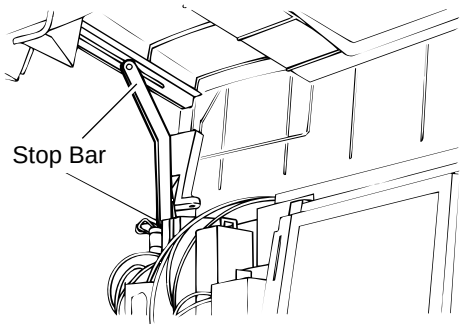
In addition to the maintenance procedures listed above, this chapter also includes procedures for the following:

- **REPLACEMENTS:**
  Replace reagents.
  Replace the piercer.
  Replace the hand clipper.
  Replace the rubber plate No. 39.
  Replace the anti-shock rubber No. 49.
  Replace the fuses.
  Replace the belt No. 6 (of mixing motor).

- **RESET THE COUNTER:**
  Reset the cycle counter of system units, such as SRV, after executing maintenance.

- **FORMAT FD:**
  Format a 3.5 inch floppy disk for use on the SF-3000.

WARNING! When working with the front cover open, make sure that the stop bar is in place.



2. SF-3000 MAINTENANCE CHECK LIST

Year and Month

PERIODICAL MAINTENANCE:

Daily:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Shutdown																
PU Trap Chamber Fluid Check																
Initial:																
Daily:	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Shutdown																
PU Trap Chamber Fluid Check																
Initial:																

Weekly:	**Date/Initial**	**Date/Initial**	**Date/Initial**	**Date/Initial**	**Date/Initial**
Clean SRV Tray					
WBC Detector Cleaning Sequence					

Monthly:	**Date/Initial**
Clean Vacuum Orifice	
Waste Chamber Cleaning Sequence	
Clean SRV	

Yearly:
Visual Inspection of Laser Unit
Date/Initial

AS NEEDED:

Procedure:	**Date/Initial**
Clean Manual Rinse Mechanism	
RBC Aperture Clog Removal Sequence	
RBC Detector Cleaning Sequence	
Clean RBC Aperture	
Remove WBC Flow Cell Air Bubble	
Sheath Flow Reagent Replace Sequence	
Replace Waste Container (if used)	

REPLACEMENTS:

Item:	**Date/Initial**
Piercer	
Hand Clippers	
Rubber Plate No. 39	
Anti-Shock Rubber No. 49	
Fuse	
Motor Belt No. 6	

3. DAILY MAINTENANCE

3.1 Clean Detector Chamber and Manometers (Shutdown)

The shutdown sequence permits you to automatically clean the WBC flow cell, RBC detector chamber and manometer and HGB flow cell. Clean these components at the end of each day's analyses or at least once every 24 hours if you use the instrument continuously.

NOTE: If the auto sampler unit or manual CP unit is installed, the piercer needle is also cleaned during the shutdown sequence.

(1) Press the [Shutdown] key from the root menu.

NOTE: If the [Shutdown] key is not displayed on the LCD, press [More] to change the displayed root menus.

(2) The Shutdown Execute window as shown below will appear. Press [Cancel] key to cancel the program.

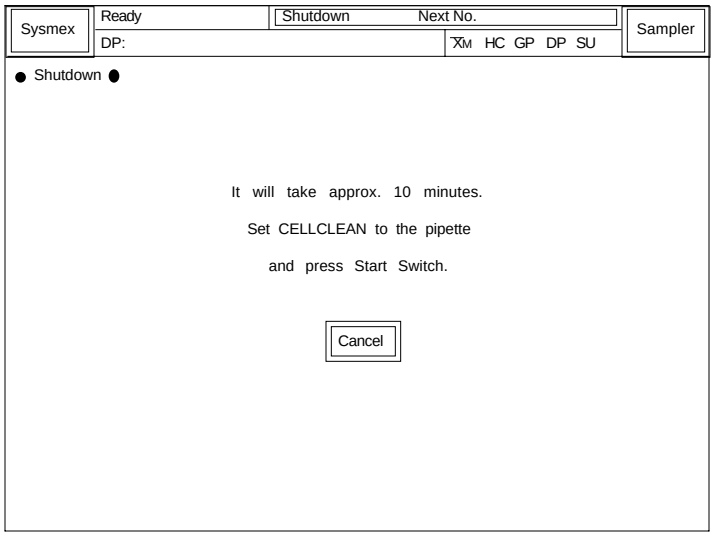


Figure 5-3-1: Shutdown Execute Window

WARNING! CELLCLEAN (or 5% filtered sodium hypochlorite) is a strong alkaline solution. Avoid contact with it. If you get it on your skin or clothing, immediately wash it off with excess water.

(3) Position the CELLCLEAN [or 5% filtered sodium hypochlorite (bleach)] into the manual aspiration pipette as shown in Figure 5-3-2; then press the Start Switch. Do not remove the CELLCLEAN while the READY LED is blinking as CELLCLEAN is being aspirated.

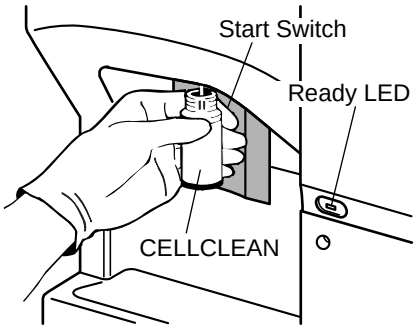


Figure 5-3-2: Introduce CELLCLEAN

(4) After the READY LED turns off and the alarm beeps three times, remove the CELLCLEAN.

(5) The shutdown sequence will start. During shutdown sequence, "Shutdown in Progress" is displayed on the LCD.

(6) After the shutdown sequence is completed, a continuous beep will sound and the Shutdown Complete screen will appear.

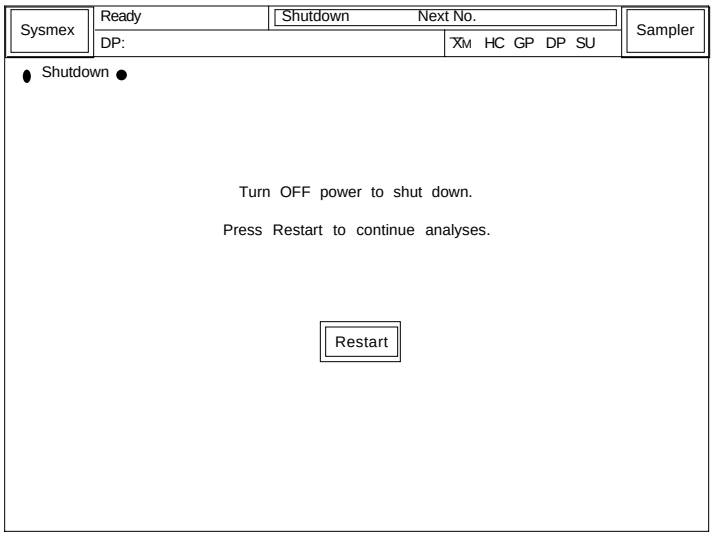


Figure 5-3-3: Shutdown Complete Screen

(7) If you are going to shutdown the instrument, turn the Main Unit power OFF. Turn the printers OFF, if attached.

NOTE: If you are going to continue to operate, perform a background check by pressing the [Restart] key displayed on the LCD.

3.2 Remove Fluid from Pneumatic Unit Trap Chamber

At the end of each day's analyses, check the fluid level in the pneumatic unit trap chamber. Discard any fluid that has collected.

WARNING! The contents in the Trap Chamber should be considered potentially biohazardous. Do not handle the Trap Chamber without proper protective equipment. Wear rubber gloves when discarding the fluid. Wash your hands with an antiseptic solution after completing the procedure.

(1) Turn OFF the power to the Main Unit. Wait at least 30 seconds to release the pressure and vacuum accumulated in the pneumatic lines.

(2) Verify that the pneumatic gauges on the Pneumatic Unit front show the zero level.

(3) Turn the trap chamber counterclockwise and remove. See Figure below.

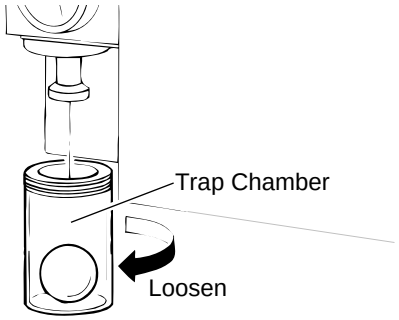


Figure 5-3-4: Trap Chamber (Front of the Pneumatic Unit)

(4) Discard the fluid; then reattach the chamber.

CAUTION: If fluid collects every day, contact a Sysmex service representative.

(5) Keep your log on the maintenance check list.

4. WEEKLY MAINTENANCE

4.1 Clean SRV Tray

Clean the tray under the Sample Rotor Valve approximately once a week, or every 600 samples, as described below.

> **WARNING!** The SRV and Tray should be considered potentially biohazardous. Do not handle the SRV or the Tray without proper protective equipment. Wear rubber gloves when cleaning. Wash your hands with an antiseptic solution after completing the procedure.

(1) Turn OFF the power to the Main Unit. Wait at least 30 seconds to release the pressure and vacuum accumulated in the pneumatic lines.

(2) Open the front cover of the Main Unit and set the stop bar in position so that the cover will not close accidentally.

(3) Remove the SRV Tray by pulling it to the left. See Figure 5-4-1.

> **CAUTION:** When removing the SRV tray, do not loosen the thumbscrew fixing the Manual Aspiration Pipette on the unit.

(4) Rinse the tray with water and wipe dry. See Figure 5-4-2.

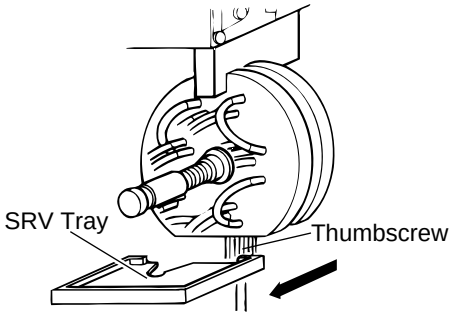


Figure 5-4-1: Remove SRV Tray (View from the instrument left side)

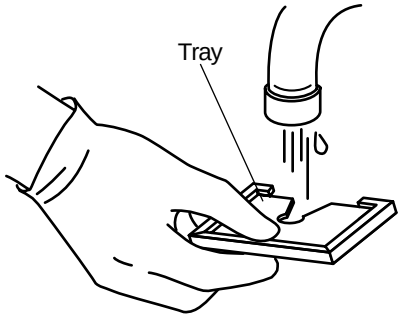


Figure 5-4-2: Rinse SRV Tray

(5) Reattach the tray in its original position.

CAUTION:
- Replace the tray in the correct position.
- Make sure that the thumbscrew on the Manual Aspiration Pipette is tightened.

(6) Release the stop bar; then close the front cover.

(7) Record the cleaning on the maintenance check list.

4.2 Execute Clean WBC Detector Sequence

Clean the WBC flow cell and the reaction chambers once a week, or every 600 samples, and reset the counter as described below.

NOTE: After every 600 cycles or a week after the previous cleaning, the message "Clean the WBC Detector" will be displayed at power ON.

WARNING! The WBC reaction chambers should be considered potentially biohazardous. Do not handle the chambers without proper protective equipment. Wear rubber gloves when executing this procedure. Wash your hands with an antiseptic solution after completing the procedure.

(1) Press the [Mainte.] key from the root menu. The Maintenance second menu will be displayed.

NOTE: If the [Mainte.] key is not displayed on the LCD, press [More] to change the displayed root menus.

Figure 5-4-3: Maintenance Second Menu

(2) Press [Service Sequence] key. The Service Sequence submenu will appear.

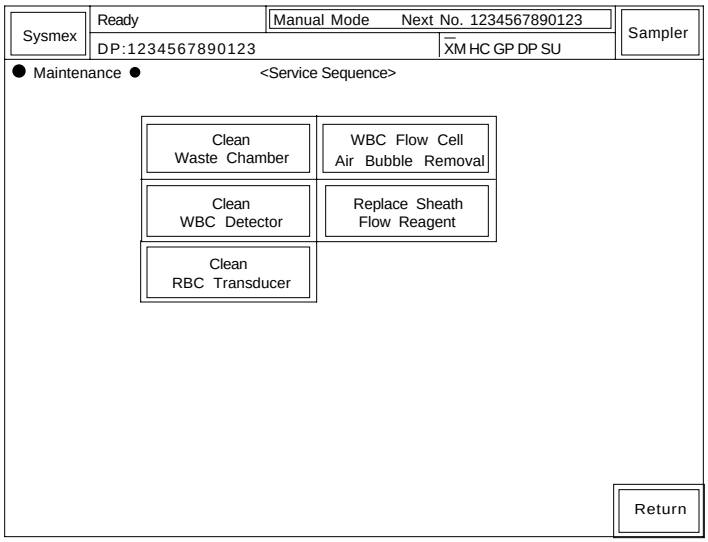


Figure 5-4-4: Service Sequence Submenu

(3) Press [Clean WBC Detector] key. The message "It will take approx. 5 min. Press Start Switch." appears.
Pressing [Cancel] cancels the program without cleaning and returns to the Service Sequence submenu display.

Figure 5-4-5: Clean WBC Detector Execute Message

(4) Press the Start Switch. The reagent is discharged from the WBC Reaction Chambers.

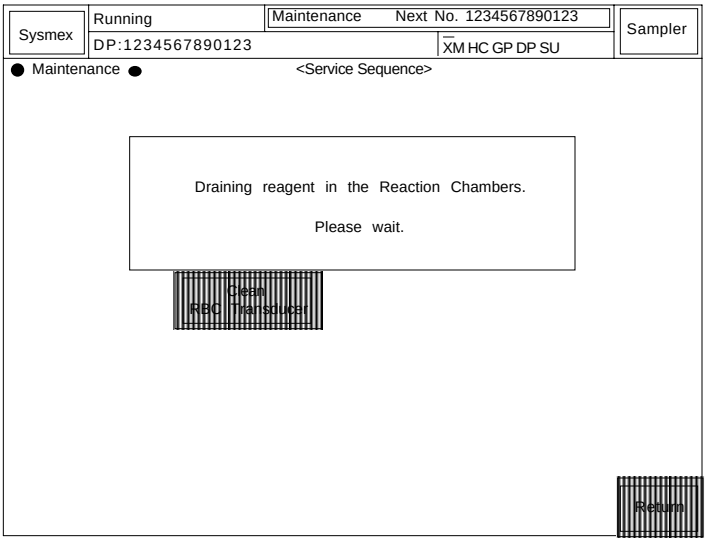


Figure 5-4-6: Cleaning WBC Detector Message (1)

(5) When the reagent is discharged from the Reaction Chambers, the message "Place 1 mL each of CELLCLEAN both in the Reaction Chambers 1 and 2. Press Start Switch." will appear.

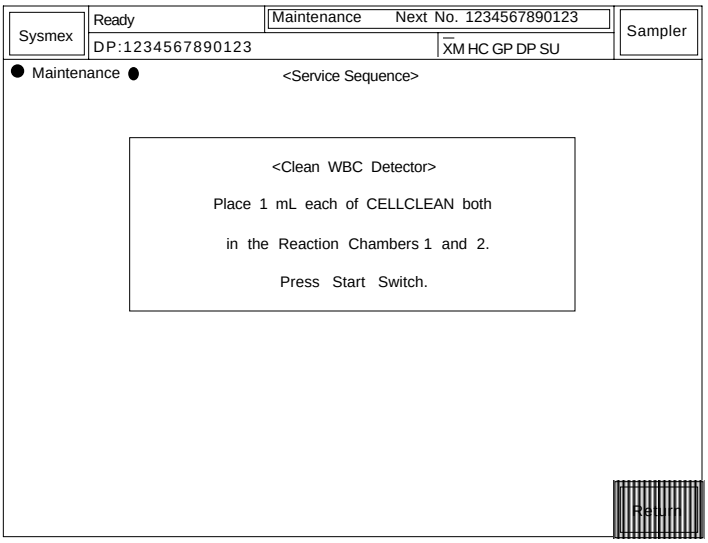


Figure 5-4-7: Cleaning WBC Detector Message (2)

(6) Open the front cover and set the stop bar in position.

WARNING! When working with the front cover open, make sure that the stop bar is in place.

WARNING! CELLCLEAN (or 5% filtered sodium hypochlorite) is a strong alkaline solution. Avoid contact with it. If you get it on your skin or clothing, immediately wash it off with excess water.

(7) Use the provided syringe (Mini - Pet No. 10) to pour 1 mL each of CELLCLEAN [or 5% filtered sodium hypochlorite (bleach)] into the reaction chambers as shown in Figure 5-4-8.

CAUTION:
- Do not pour CELLCLEAN more than 2.0 mL into the chamber to avoid overflow; this can result in system malfunction.
- If reagent spills on painted surfaces of the instrument, immediately wipe it up with a damp tissue.

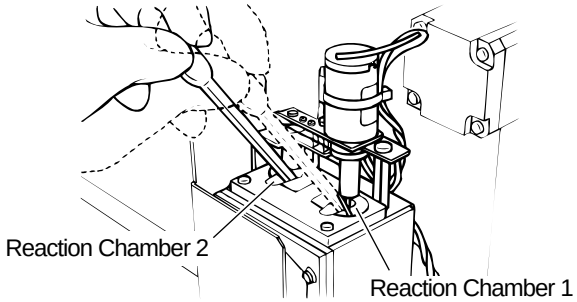


Figure 5-4-8: Place CELLCLEAN

(8) Press the Start Switch. The cleaning sequence will start. During the cleaning sequence, the elapsed time is displayed as shown below.

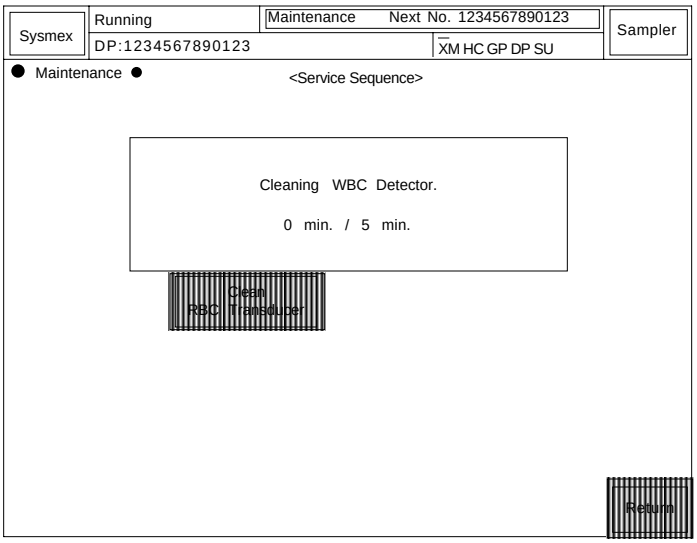


Figure 5-4-9: Cleaning WBC Detector Screen (3)

(9) After the cleaning sequence is completed, the instrument automatically performs auto rinse and returns to Ready status.

(10) Release the stop bar and close the front cover.

(11) Reset the counter of the WBC Detector. Refer to *Section 9: Reset the Counter* in this chapter.

NOTE:	Make sure to reset the counter. If not, the message "Clean the WBC Detector" will remain on the LCD.

(12) Record the cleaning on the maintenance check list.

5. MONTHLY MAINTENANCE

5.1 Clean Orifice

Clean the orifice once a month, or every 2500 samples, and reset the counter as described below.

NOTE:	After every 2500 cycles or a month after the previous cleaning, the message "Clean the Orifice" will be displayed at power ON.

WARNING!	The orifice should be considered potentially biohazardous. Do not handle this opening without proper protective equipment. Wear rubber gloves when cleaning. Wash your hands with an antiseptic solution after completing the procedure.

(1) Turn OFF the power to the Main Unit. Wait at least 30 seconds to release the pressure and vacuum accumulated in the pneumatic lines.

(2) Remove the orifice by unscrewing counterclockwise. See Figure 5-5-1.

(3) Use the cleaning tool provided as a supply part to remove all dirt from the orifice. See Figure 5-5-2.

NOTE:	The cleaning tool will only fit into the orifice approximately 1.0 cm.

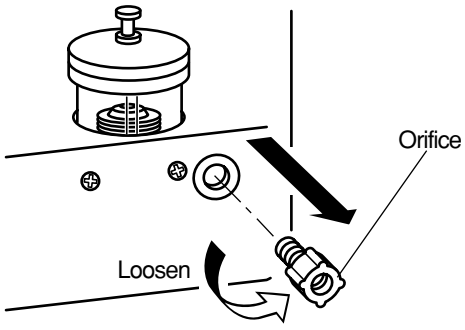


Figure 5-5-1: Remove Orifice (Main Unit Left Side View)

Figure 5-5-2: Clean Orifice

(4) Rinse the orifice with tap water.

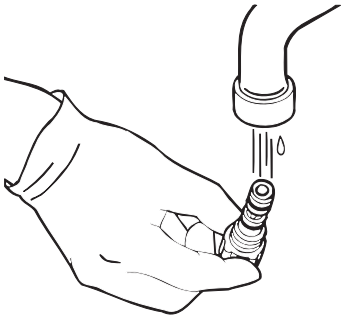


Figure 5-5-3: Rinse Orifice

(5) Check the orifice for dirt, and wipe off any water.

(6) Reattach the orifice to its original position.

(7) Reset the counter of the Vacuum Orifice. Refer to *Section 9: Reset the Counter* in this chapter.

NOTE:	Make sure to reset the counter after cleaning. If not, the message "Clean the Orifice" will remain on the LCD.

(8) Record the cleaning on the maintenance check list.

5.2 Execute Clean Waste Chamber Sequence

Clean the waste chambers and trap chambers once a month, or every 2500 samples, and reset the counter as described below.

NOTE:	After every 2500 cycles or a month after the previous cleaning, the message "Clean the Waste Chamber" will be displayed at power ON.

(1) Press the [Mainte.] key from the root menu. The Maintenance second menu will be displayed.

NOTE:	If the [Mainte.] key is not displayed on the LCD, press [More] to change the displayed root menus.

Figure 5-5-4: Maintenance Second Menu

(2) Press [Service Sequence] key. The Service Sequence submenu will appear.

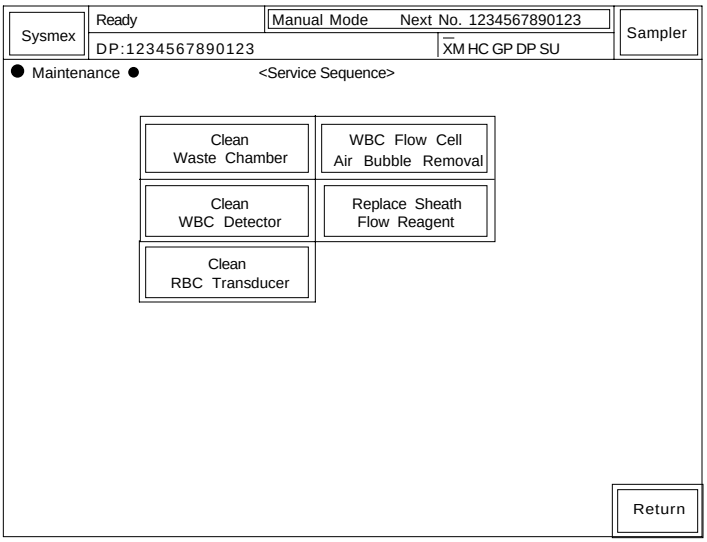


Figure 5-5-5: Service Sequence Submenu

(3) Press [Clean Waste Chamber] key. The message "It will take approx. 20 min. Press Start Switch." appears.
Pressing [Cancel] cancels the program without cleaning and returns to the Service Sequence submenu display.

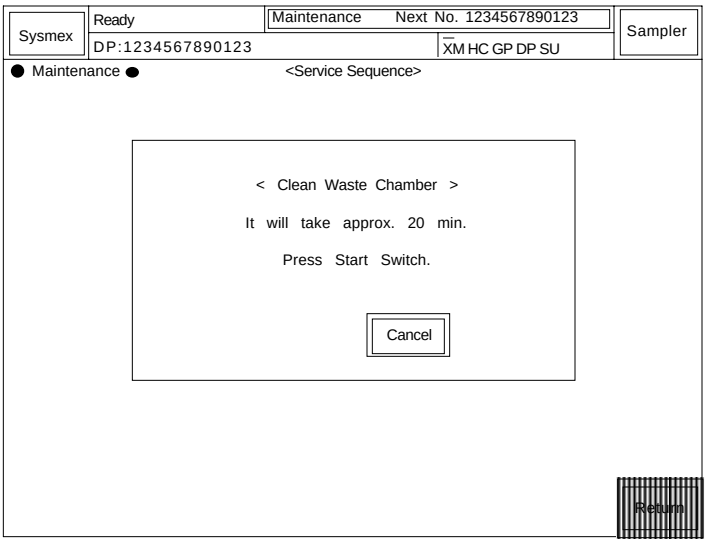


Figure 5-5-6: Clean Waste Chamber Execute Message

(4) Press the Start Switch. The reagent is discharged from the WBC Reaction Chambers.

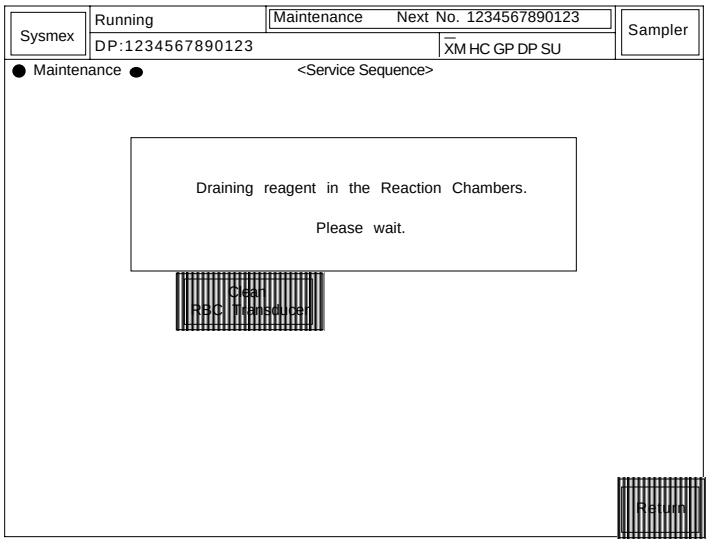


Figure 5-5-7: Cleaning Waste Chamber Message (1)

(5) When the reagent is discharged from the Reaction Chambers, the message "Place 1 mL each of CELLCLEAN both in the Reaction Chambers 1 and 2. Press Start Switch." will appear.

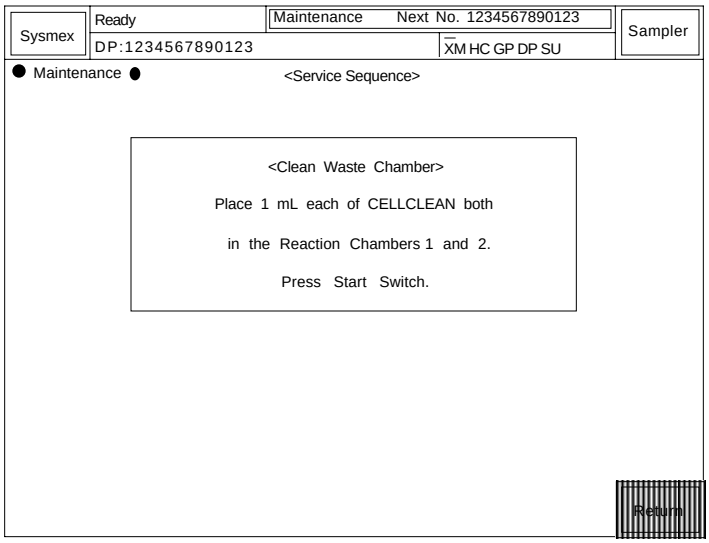


Figure 5-5-8: Cleaning Waste Chamber Message (2)

(6) Open the front cover and set the stop bar in position.

WARNING! When working with the front cover open, make sure that the stop bar is in place.

WARNING! CELLCLEAN (or 5% filtered sodium hypochlorite) is a strong alkaline solution. Avoid contact with it. If you get it on your skin or clothing, immediately wash it off with excess water.

(7) Use the provided syringe (Mini - Pet No. 10) to pour 1 mL each of CELLCLEAN [or 5% filtered sodium hypochlorite (bleach)] into the reaction chambers as shown in Figure 5-5-9.

CAUTION:
- Do not pour CELLCLEAN more than 2.0 mL into the chamber to avoid overflow; this can result in system malfunction.
- If reagent spills on painted surfaces of the instrument, immediately wipe it up with a damp tissue.

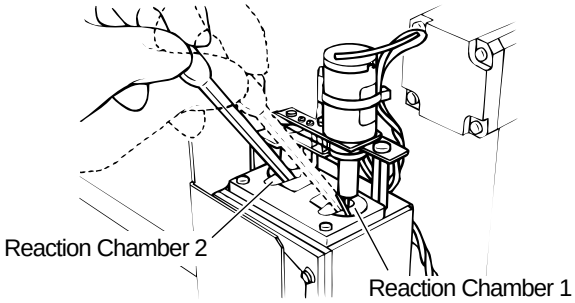


Figure 5-5-9: Place CELLCLEAN

(8) Press the Start Switch. The cleaning sequence will start. During the cleaning sequence, the elapsed time is displayed as shown below.

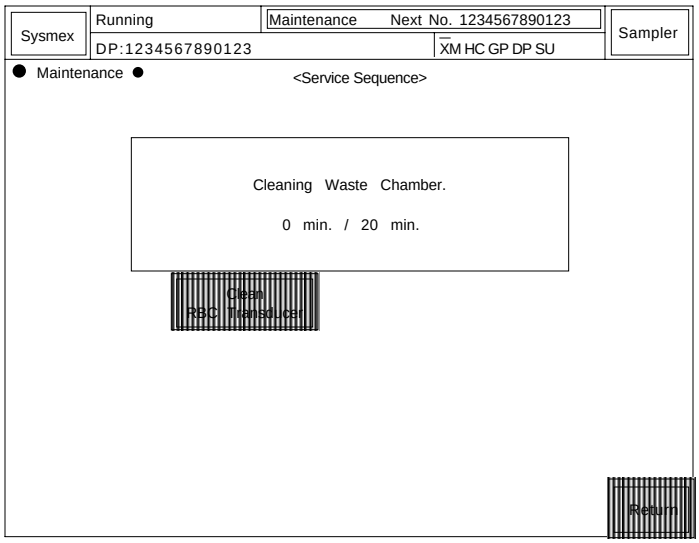


Figure 5-5-10: Cleaning Waste Chamber Screen (3)

(9) After the cleaning sequence is completed, the instrument automatically performs auto rinse and returns to the Ready status.

(10) Release the stop bar and close the front cover.

(11) Reset the counter of the Waste Chamber. Refer to *Section 9: Reset the Counter* in this chapter.

NOTE: Make sure to reset the counter. If not reset, the message "Clean the Waste Chamber" will remain on the LCD.

(12) Record the cleaning on the maintenance check list.

5.3 Clean Sample Rotor Valve (SRV)

Clean the sample rotor valve once a month, or every 2500 samples, and reset the counter as described below.

NOTE: After every 2500 cycles or a month after the previous cleaning, the message "Clean the SRV." will be displayed at power ON.

WARNING! The SRV should be considered potentially biohazardous. Do not handle the SRV without proper protective equipment. Wear rubber gloves when cleaning. Wash your hands with an antiseptic solution after completing the procedure.

CAUTION: If reagent spills on painted surfaces of the instrument, immediately wipe it up with a damp tissue.

(1) Run a quality control prior to the SRV cleaning. The data will be used for the data verification in step (17).

(2) Turn OFF the power to the Main Unit. Wait at least 30 seconds to release the pressure and vacuum accumulated in the pneumatic lines.

(3) Open the front cover of the Main Unit, and set the stop bar in place to avoid accidental closure.

(4) Remove the SRV Tray by pulling it toward you. See Figure 5-5-11.

CAUTION: When removing the SRV tray, do not loosen the thumbscrew fixing the Manual Aspiration Pipette on the unit.

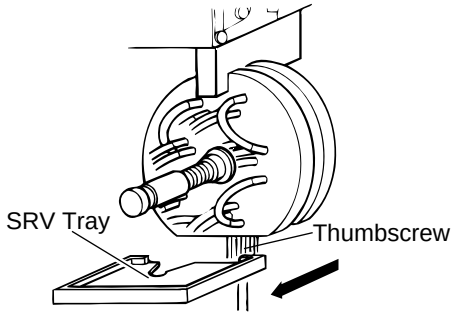


Figure 5-5-11: Remove SRV Tray (View from the instrument left side)

(5) Gently pull down the Manual Rinse Mechanism as shown in Figure 5-5-12.

CAUTION: Pull down the Rinse Mechanism to the lowest position to prevent the Manual Aspiration Pipette from bending.

(6) Place a tissue or cloth under the SRV to absorb any reagent.

(7) Turn the SRV thumbscrew counterclockwise to remove it (see Figure 5-5-13).

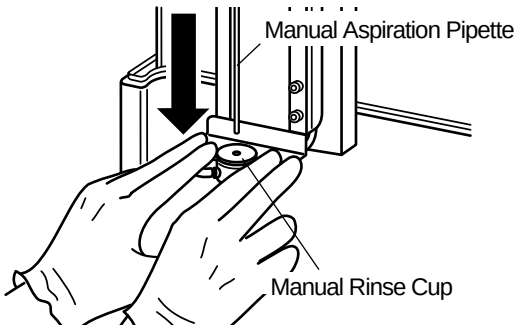


Figure 5-5-12: Manual Rinse Mechanism

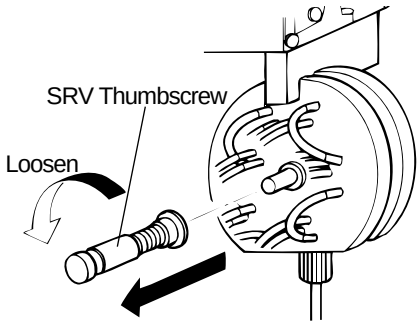


Figure 5-5-13: Remove Thumbscrew

CAUTION:
- Do not pull the valve sections out too far, the tubes connected to the rear fixed valve might become damaged or disconnected.
- Take care not to bend the Manual Aspiration Pipette when pulling out the valve.

(8) Pull the valve sections gently toward you. See Figure 5-5-14.

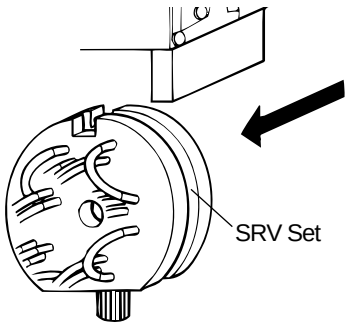


Figure 5-5-14: Remove SRV Set
(View from the Instrument Left Side)

CAUTION: When a fixed valve is removed, reagent might leak from the tubes. Prepare on hand a cloth or tissue to absorb any reagent.

(9) Remove the front fixed valve by gently pulling toward you, then remove the rotation valve. See Figure 5-5-15.

NOTE: If the sections of the valve are stuck together, you can remove them by slightly pulling toward you, gently turning, and then sliding them out.

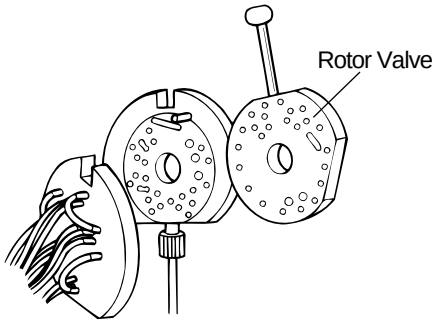


Figure 5-5-15: Remove Rotor Valve

WARNING! CELLCLEAN (or 5% filtered sodium hypochlorite) is a strong alkaline solution. Avoid contact with it. If you get it on your skin or clothing, immediately wash it off with excess of water.

CAUTION:
- Do not use solvents other than CELLCLEAN (or 5% filtered sodium hypochlorite (bleach)).
- The sampling valves are adequately resistant to corrosion from CELLCLEAN; however, completely wipe off the CELLCLEAN to prevent problems in other parts of the instrument.
- Do not damage the sampling valve surface in any way; this can cause leaks.

(10) Using lint-free gauze soaked with distilled water, clean the surfaces of the fixed valve and rotation valve. If you use both distilled water and 1:10 diluted CELLCLEAN (or 5% filtered sodium hypochlorite (bleach)), you can easily remove adhered contaminants. See Figure 5-5-16.

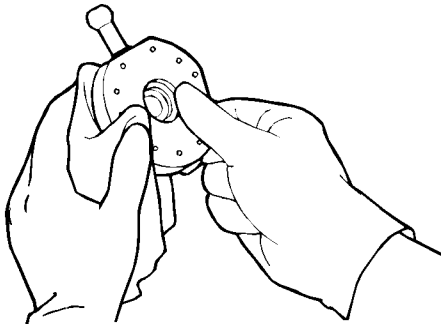
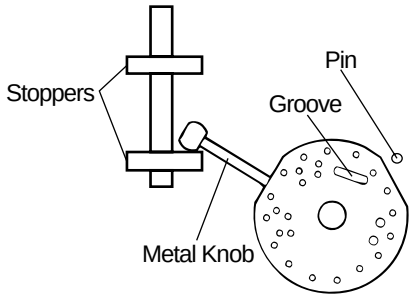


Figure 5-5-16: Clean Valves

(11) Make sure that no contaminants or dust adhere to the valve contact surfaces. Contaminants and dust can cause the sampling valve to malfunction.

(12) Reassemble the sample rotor valve in the reverse order. Tighten the thumbscrew.

CAUTION: Position the rotation valve so that the side with the groove faces the front and the metal knob is between the two stoppers and touches the bottom stopper.



View from the Instrument Left Side

(13) Flush the SRV tray with tap water, and replace it.

(14) Slowly and gently push up the Manual Rinse Mechanism.

(15) Release the stop bar and close the front cover.

(16) Turn ON the power. After executing auto rinse, confirm that all background values are within the acceptable limits. If a background error occurs, perform additional background checks as needed. If the error persists, clean the SRV again, or refer to *Chapter 8: Troubleshooting.*

Table 5-5-1: Acceptable Background Limits

Parameters	Acceptable Limits	
WBC/BASO Channel	0.1	[x $10^3/\mu L$]
DIFF Channel	0.1	[x $10^3/\mu L$]
RBC	0.02	[x $10^6/\mu L$]
HGB	0.1	[g/dL]
PLT	10	[x $10^3/\mu L$]

(17) Run a quality control blood to make sure that the performance of the Sample Rotor Valve is acceptable.

(18) Reset the SRV counter by referring to *Section 9: Reset the Counter* in this chapter.

NOTE: Make sure to reset the counter. If not reset, the message "Clean the SRV" will remain on the LCD.

(19) Record the cleaning on the maintenance check list.

6. YEARLY MAINTENANCE

6.1 Visual Inspection for Laser Safety

Once a year, visually inspect the optical system to verify that there is no potential of laser light leakage and that proper warning labels are in place.

WARNING! Never open the optical system cover. Up to 2 mW of laser light is accessible inside this unit and the beam can damage your eyes.

(1) Turn OFF the power to the Main Unit. Remove the Main Unit left side cover by loosening the 2 screws with a screwdriver (Phillips).

(2) Verify that two warning labels "DANGER, Laser Light when open, AVOID DIRECT EYE EXPOSURE" are visible as shown in Figure 5-6-1.

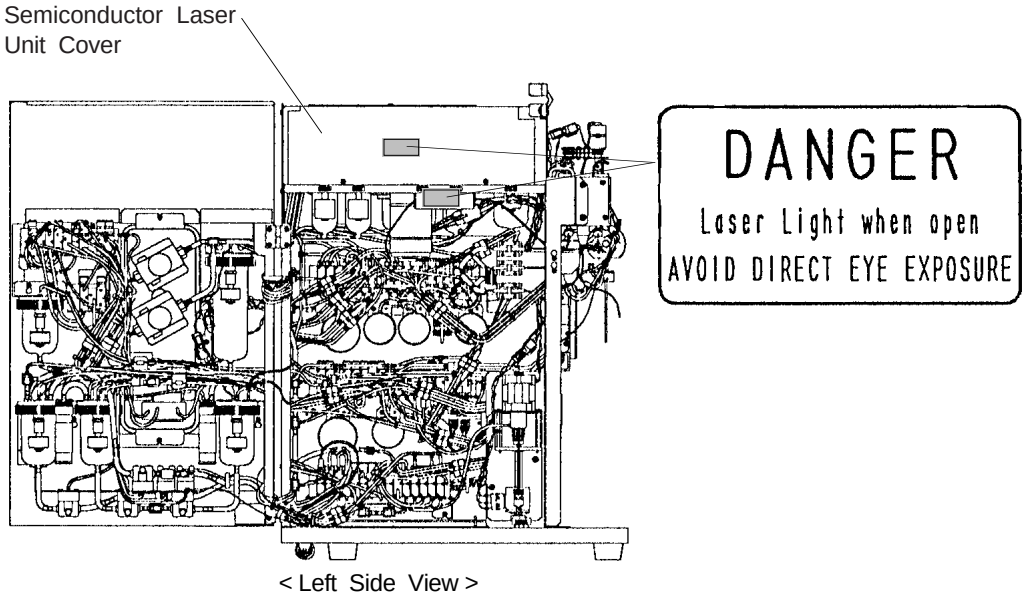


Figure 5-6-1: Location of Laser Unit and Labels (Left Interior of the Main Unit)

NOTE: A third warning label is visible as shown in Figure 5-6-2 when the laser unit cover is removed.

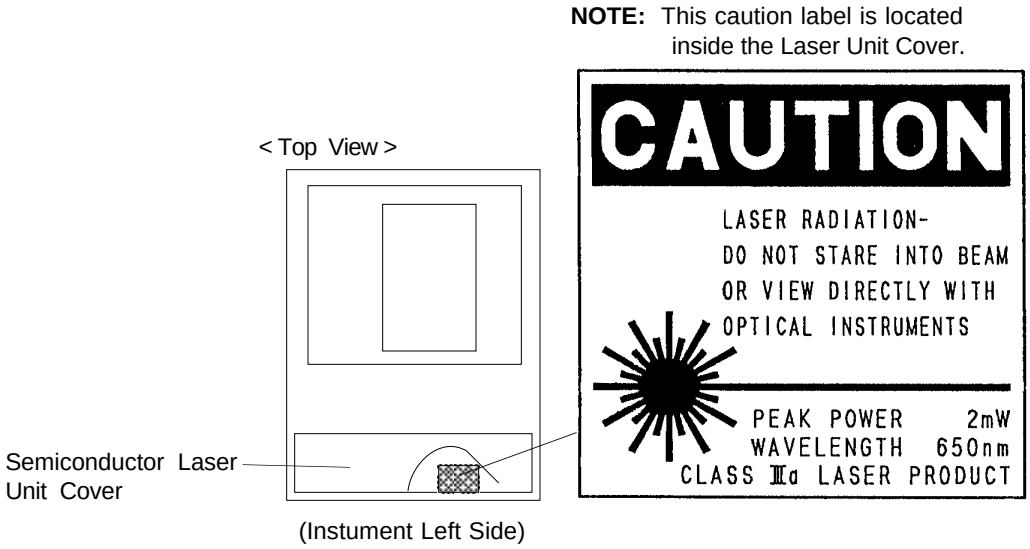


Figure 5-6-2: Location of Warning Label inside the Laser Cover (Main Unit - Top View)

(3) Verify that all seals and screws are secured, the metal panels of the optical unit cover are not loose or distorted, and that the entire assembly is secure.

(4) If the optical system cover has detectable opening, defective or damaged parts, contact Sysmex service representative to repair, replace or adjust it before turning on the power to the instrument.

(5) If the visual inspection is acceptable, turn ON the power to the Main Unit.

WARNING! TURN OFF THE POWER TO THE MAIN UNIT if the system is obviously leaking laser light. Laser light is dangerous to your eyes by direct contact.

WARNING! Do not place any part of your body inside the open left side cover.

(6) Stand directly at the left side of the instrument and check for the appearance of (red) laser light leaking from the optical system cover.

(7) If any light leakage is evident, IMMEDIATELY TURN OFF THE POWER TO THE MAIN UNIT and disconnect the power cord from the AC outlet. Contact Sysmex service representative for repair.

(8) Record the inspection on the maintenance check list.

7. AS NEEDED MAINTENANCE

7.1 Clean Manual Rinse Mechanism

If the manual rinse mechanism becomes dirty or clogged, clean it as described below.

> **WARNING!** The manual rinse mechanism should be considered potentially biohazardous. Do not handle this unit without proper protective equipment. Wear rubber gloves when cleaning. Wash your hands with an antiseptic solution after completing the procedure.

(1) Turn OFF the power to the Main Unit. Wait at least 30 seconds to release the pressure and vacuum accumulated in the pneumatic lines.

(2) Open the front cover and place the stop bar in position.

(3) Gently pull down the manual rinse cup to the lowest position until the rinse cup is released from the manual aspiration pipette. See Figure 5-7-1.

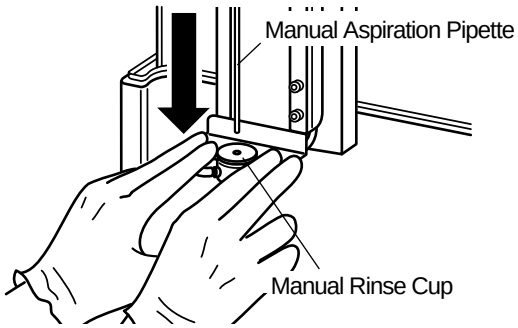


Figure 5-7-1: Pull Down the Rinse Cup

(4) Pull the rinse cup forward to you (arrow ①) and disconnect the two tubes (arrows ② and ③). See Figure 5-7-2.

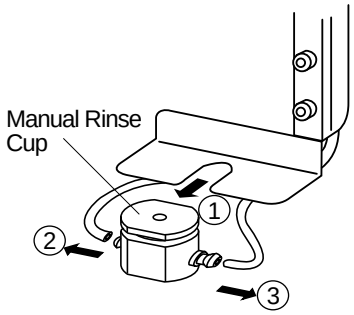


Figure 5-7-2: Disconnect the Tubes

(5) Rinse the manual rinse cup with tap water.

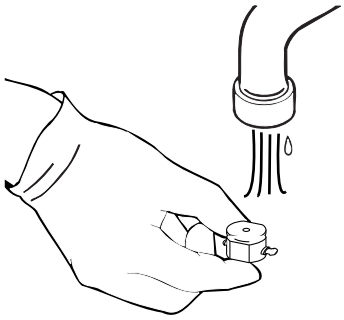


Figure 5-7-3: Rinse the Rinse Cup

(6) Use a dry gauze to wipe the rinse cup.

(7) Reconnect the two tubes (arrows ① and ②). Then replace the manual rinse cup to its original position (arrow ③). The smaller diameter tube should route behind the rinse cup mechanism.

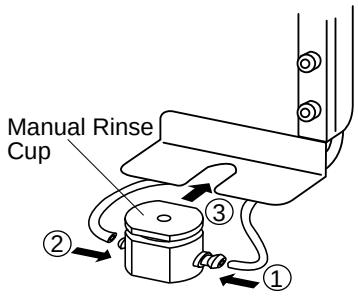


Figure 5-7-4: Reconnect the Tubes

(8) Gently insert the pipette into the manual rinse cup and push up the rinse cup mechanism to the uppermost position.

CAUTION:
- To prevent the manual aspiration pipette from bending, gently insert the pipette into the manual rinse cup.
- To prevent a "Rinse Motor Function Error", make sure that the rinse cup mechanism is at its uppermost position.

(9) Turn ON the power.

(10) Record the cleaning on the maintenance check list.

7.2 Execute RBC Aperture Clog Removal Sequence

If the error message "RBC Count Time Too Long" or "RBC Slow To Start" appears on the LCD, execute a clog removal sequence as described below.

(1) Press the [Mainte.] key from the root menu. The Maintenance second menu will be displayed.

NOTE: If the [Mainte.] key is not displayed on the LCD, press [More] to change the displayed root menus.

Figure 5-7-5: Maintenance Second Menu

(2) Press the [Clog Removal] key to execute the clog removal sequence.

(3) The message "Removing Clog" appears on the LCD.

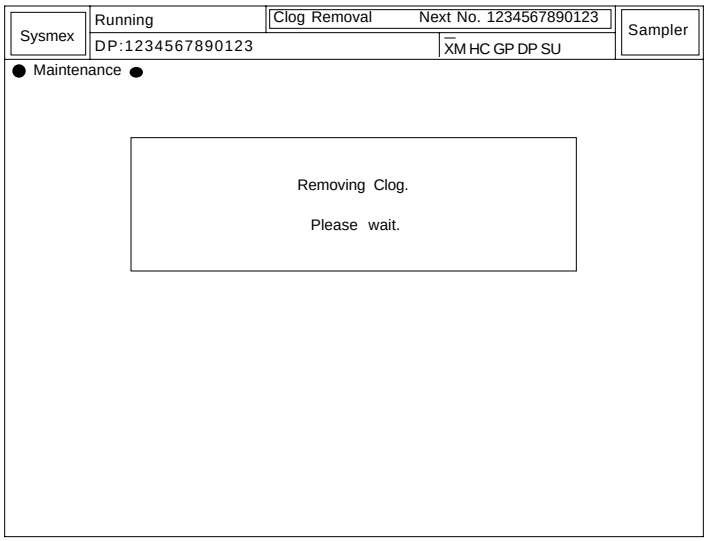


Figure 5-7-6: Clog Removal Sequence Display

(4) After the Clog Removal sequence is completed, the instrument returns to the ready status.

(5) Record the clog removal on the maintenance check list.

NOTE:	If the error persists, execute the clean transducer sequence by referring to the following *Section 7.3.*

7.3 Execute Clean RBC Transducer Sequence

If an aperture clog persists even after clog removal sequence has been executed, execute the clean transducer sequence as described below.

WARNING! The transducer should be considered potentially biohazardous. Do not handle the transducer without proper protective equipment. Wear rubber gloves when cleaning. Wash your hands with an antiseptic solution after completing the procedure.

(1) Press the [Mainte.] key from the root menu. The Maintenance second menu will be displayed.

NOTE: If the [Mainte.] key is not displayed on the LCD, press [More] to change the displayed root menus.

(2) Press [Service Sequence] key. The Service Sequence submenu will appear.

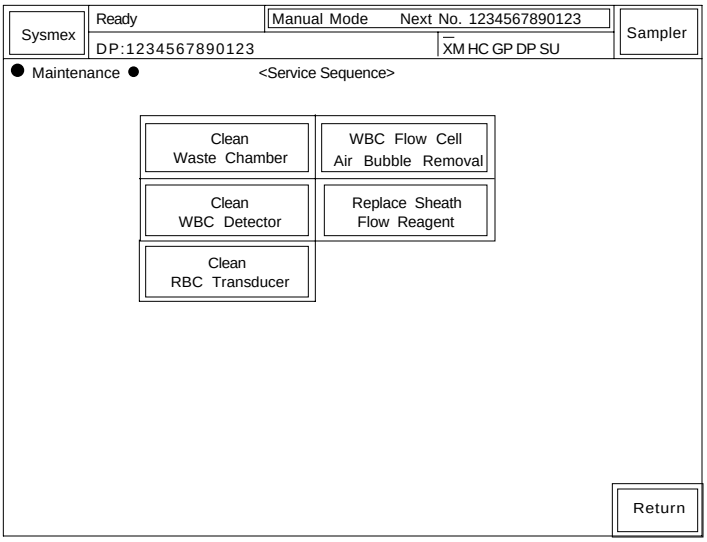


Figure 5-7-7: Service Sequence Submenu

(3) Press [Clean RBC Transducer] key. The message "It will take approx. 2 min. Press Start Switch" will be displayed.
Pressing [Cancel] cancels the program without cleaning and returns to the Service Sequence submenu display.

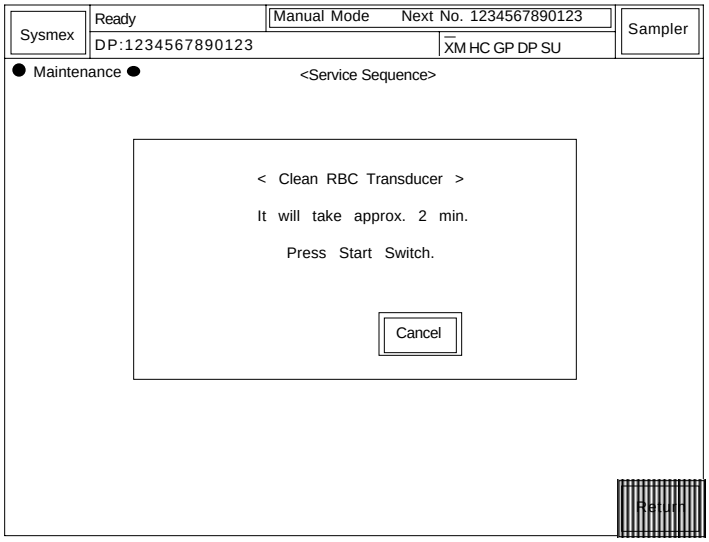


Figure 5-7-8: Clean Transducer Execute Message Window

(4) Press the Start Switch. The reagent is discharged from the detector chamber.

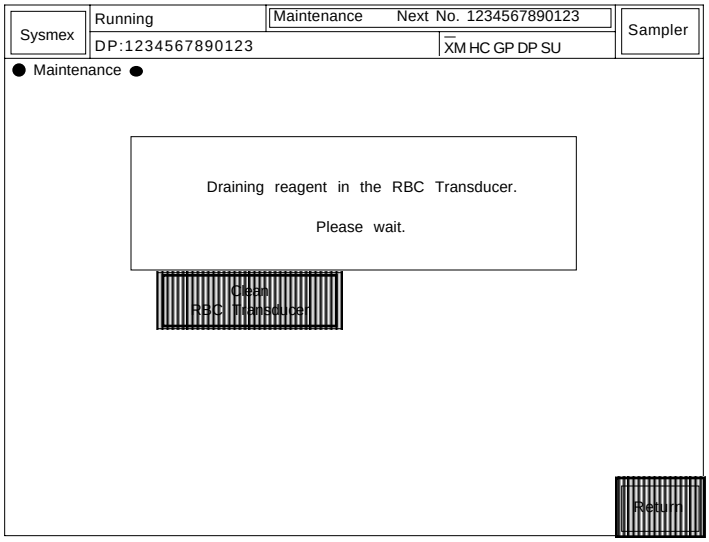


Figure 5-7-9: Cleaning Transducer Message Window (1)

(5) When the detector chamber becomes empty, the message "Place 1 mL of CELLCLEAN in the RBC Transducer and press Start Switch." will appear.

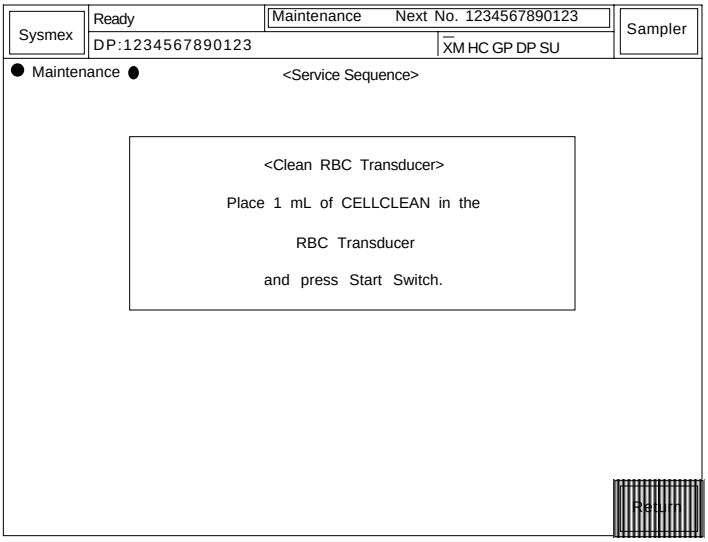


Figure 5-7-10: Cleaning Transducer Message Window (2)

(6) Open the front cover and set the stop bar in position.

WARNING! When working with the front cover open, make sure that the stop bar is in place.

(7) Remove the RBC transducer cap. See Figure 5-7-11.

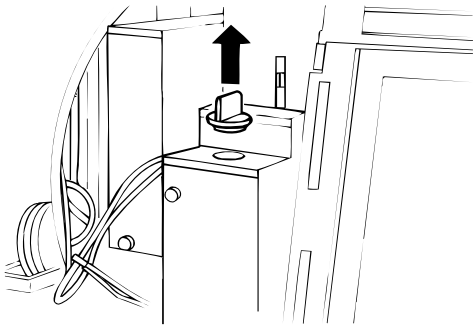


Figure 5-7-11: Remove Transducer Cap

WARNING! CELLCLEAN (or 5% filtered sodium hypochlorite) is a strong alkaline solution. Avoid contact with it. If you get it on your skin or clothing, immediately wash it off with excess water.

(8) Use the provided syringe (Mini - Pet No. 10) to pour 1.0 mL of CELLCLEAN (or 5% filtered sodium hypochlorite (bleach)) into the transducer chamber as shown in Figure 5-7-12.

CAUTION:
- To avoid overflow, do not pour more than 2.0 mL CELLCLEAN into the chamber. This can result in system malfunction.
- If reagent spills on painted surfaces of the instrument, immediately wipe it out with a damp tissue.

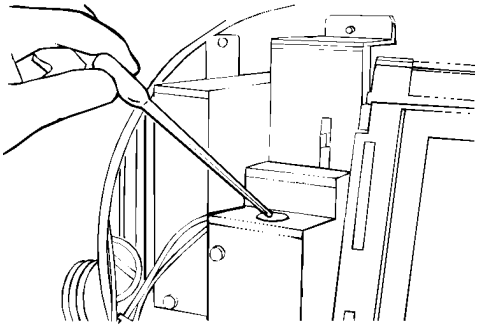


Figure 5-7-12: Place CELLCLEAN

(9) Replace the transducer cap.

(10) Press the Start Switch to execute the clean transducer sequence. The cleaning sequence will start. During the rinse sequence, the elapsed time is displayed as shown below.

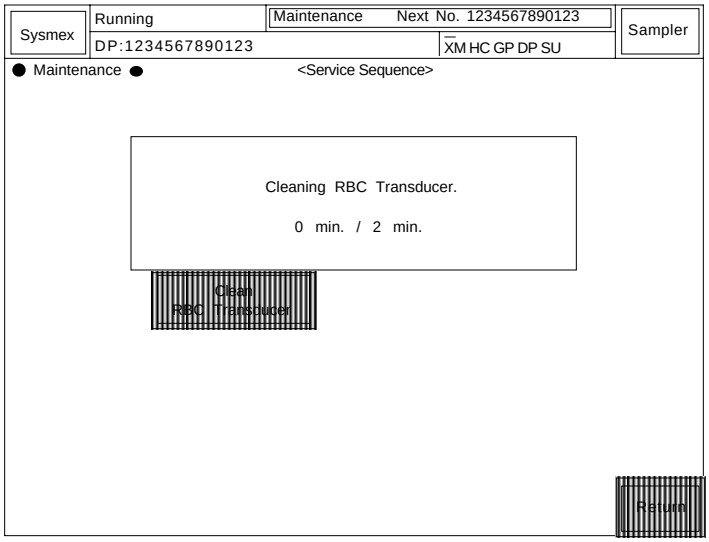


Figure 5-7-13: Cleaning Transducer Message Window (3)

(11) After the cleaning sequence is completed, the instrument automatically performs auto rinse and returns to the Ready status.

(12) Release the stop bar and close the front cover.

(13) Record the cleaning on the maintenance check list.

7.4 Clean RBC Detector Aperture

If an aperture clog persists even after clog removal and clean transducer cycles have been executed, clean the aperture as described below.

WARNING! The detector and aperture should be considered potentially biohazardous. Do not perform this procedure without proper protective equipment. Wear rubber gloves when cleaning. Wash your hands with an antiseptic solution after completing the procedure.

(1) Press the [Mainte.] key from the root menu. The Maintenance second menu will be displayed.

NOTE: If the [Mainte.] key is not displayed on the LCD, press [More] to change the displayed root menus.

(2) Press [Drain Sample] key to discharge the reagent from the RBC detector chamber.

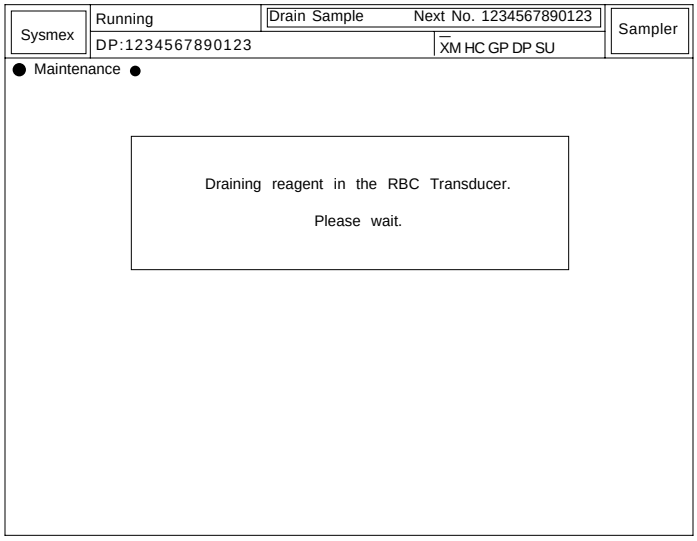


Figure 5-7-14: Press [Drain Sample]

(3) Turn OFF the power to the Main Unit. Wait at least 30 seconds to release the pressure and vacuum accumulated in the pneumatic lines.

(4) Open the front cover and set the stop bar in position.

> **WARNING!** When working with the front cover open, make sure that the stop bar is in place to avoid accidental closure.

(5) Loosen the thumbscrew and open the RBC detector cover. Make sure that the sample has been drained. See Figures 5-7-15 and 5-7-16.

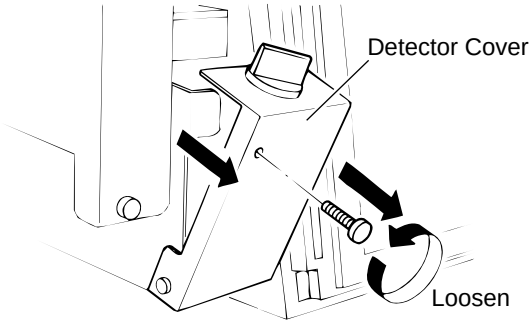


Figure 5-7-15: Open the Detector Cover

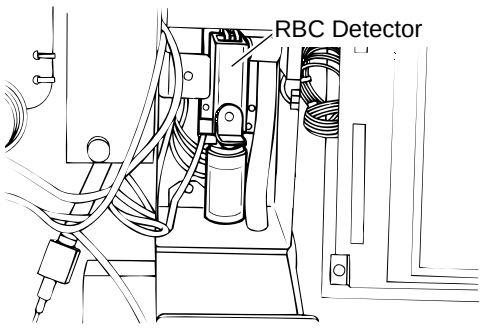


Figure 5-7-16: RBC Detector

(6) Prepare a gauze or lint-free tissue to absorb any reagent from the transducer chamber. Remove the plug to access the transducer aperture (Figure 5-7-17).

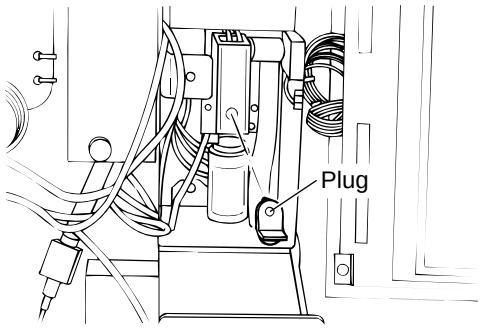


Figure 5-7-17: Remove the Plug

WARNING! CELLCLEAN (or 5% filtered sodium hypochlorite) is a strong alkaline solution. Avoid contact with it. If you get it on your skin or clothing, immediately wash it off with excess water.

(7) Apply CELLCLEAN [or 5% filtered sodium hypochlorite (bleach)] to the transducer brush provided as a supply part, and gently dab the aperture. See Figure 5-7-18.

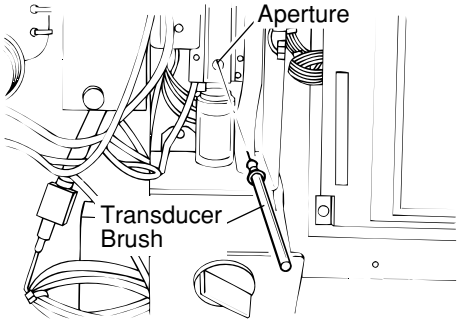


Figure 5-7-18: Dab the Aperture

NOTE: Thoroughly wash the brush after use to remove all CELLCLEAN and then store.

(8) Reattach the transducer plug.

(9) Close the detector cover. Release the stop bar and close the front cover.

(10) Turn ON the power. An auto rinse cycle will automatically be executed. Make sure that all background values are within the acceptable limits.

Table 5-7-1: Acceptable Background Limits

Parameters	Acceptable Limits
WBC/BASO Channel	0.1 [x $10^3/\mu L$]
DIFF Channel	0.1 [x $10^3/\mu L$]
RBC	0.02 [x $10^6/\mu L$]
HGB	0.1 [g/dL]
PLT	10 [x $10^3/\mu L$]

(11) Keep the cleaning record on the maintenance check list.

7.5 Execute WBC Flow Cell Air Bubbles Removal Sequence

When the scattergrams show abnormally enlarged groups of cells, air bubbles may exist in the WBC Flow Cell. At this time, remove the air bubbles as described below.

NOTE: No WBC IP message or no analysis error may occur if air bubbles exist in the WBC Flow Cell.

(1) Press the [Mainte.] key from the root menu. The Maintenance second menu will be displayed.

NOTE: If the [Mainte.] key is not displayed on the LCD, press [More] to change the displayed root menus.

Figure 5-7-19: Maintenance Second Menu

(2) Press [Service Sequence] key. The Service Sequence submenu will appear.

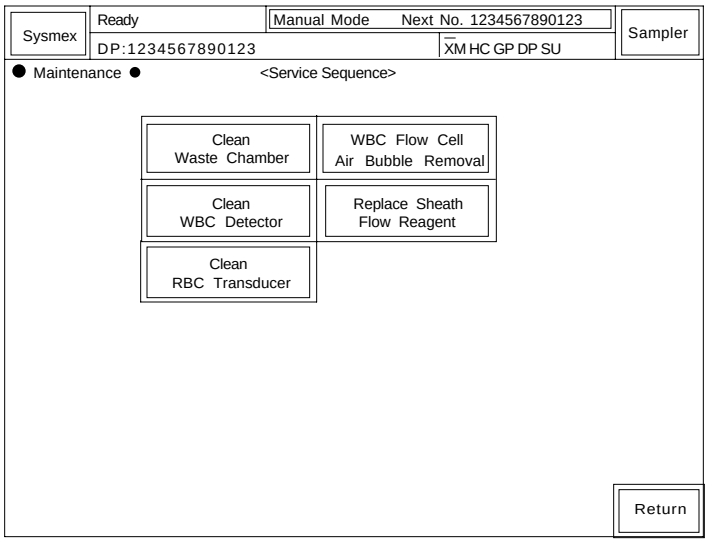


Figure 5-7-20: Service Sequence Submenu

(3) Press [WBC Flow Cell Air Bubble Removal] key. During the air bubbles removal sequence, the message shown below will appear on the LCD.

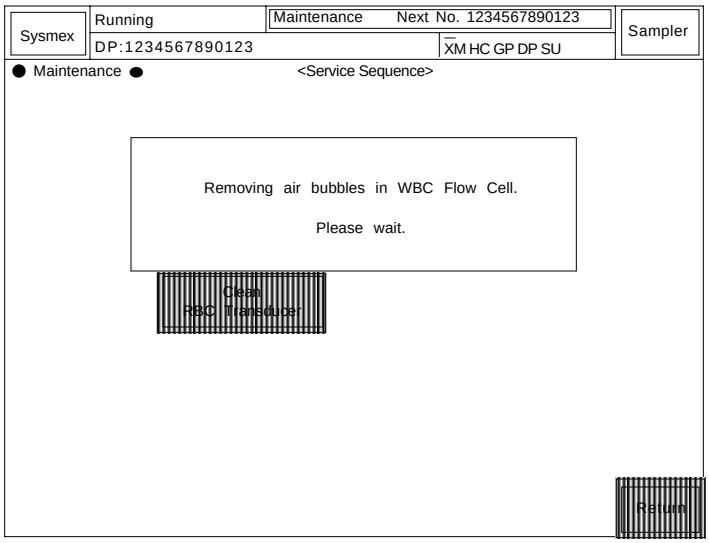


Figure 5-7-21: Removing WBC Flow Cell Air Bubbles

(4) After the rinse sequence is completed, the instrument returns to the Ready status.

(5) Keep the record on the maintenance check list.

7.6 Execute Replace Sheath Flow Reagent Sequence

When the WBC background count becomes abnormally high, the internal reservoir chamber for WBC sheath flow reagent (CELLPACK) may contain air bubbles. At this time, remove the air bubbles as described below.

(1) Press the [Mainte.] key from the root menu. The Maintenance second menu will be displayed.

NOTE: If the [Mainte.] key is not displayed on the LCD, press [More] to change the displayed root menus.

Figure 5-7-22: Maintenance Second Menu

(2) Press [Service Sequence] key. The Service Sequence submenu will appear.

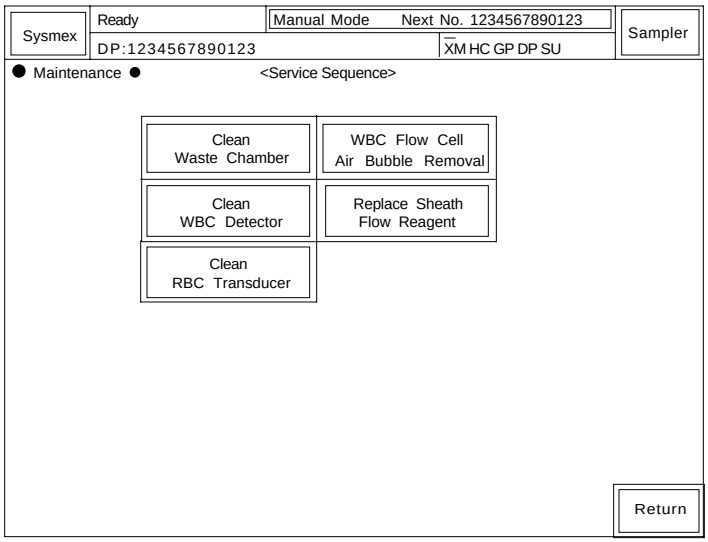


Figure 5-7-23: Service Sequence Submenu

(3) Press [Replace Sheath Flow Reagent] key. During the replacing sequence, the message shown below will appear on the LCD.

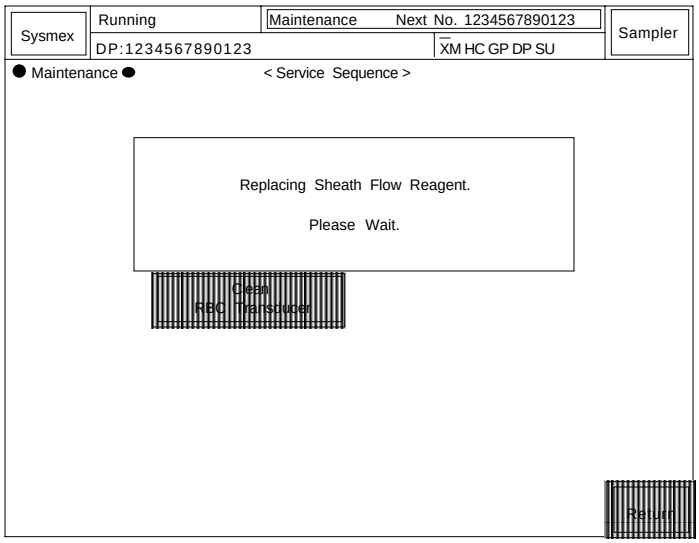


Figure 5-7-24: Replacing Sheath Flow Reagent Message

(4) After the replacing sequence is completed, the instrument returns to the Ready status.

(5) Keep the record on the maintenance check list.

7.7 Replace Waste Container (if used)

When the waste container is full, replace the container as described below.

WARNING! The waste container and contents should be considered potentially biohazardous. Do not handle the waste container without proper protective equipment. Wear rubber gloves when replacing. Wash your hands with an antiseptic solution after completing the procedure.

(1) Turn OFF the power to the Main Unit. Wait at least 30 seconds to release the pressure and vacuum accumulated in the pneumatic lines.

(2) Prepare an empty waste container, and remove the cap.

CAUTION: If using a used reagent container as the waste container, clearly indicate that the container contains waste fluid.

(3) Remove the adhesive tape holding the waste line tubing onto the waste container (see Figure 5-7-25). Carefully lift the tubing straight out from the old container.

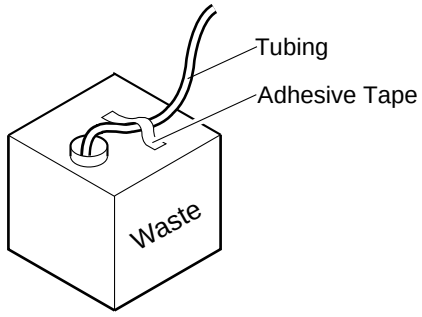


Figure 5-7-25: Waste Container

(4) Insert the tubing straight into the new waste container, and fix it with an adhesive tape.

(5) Use the cap removed in step (2) above to cap the full container. Dispose the waste in accordance with your laboratory policy and existing hospital, laboratory, and government regulations.

(6) Record the replacement on the maintenance check list.

8. REPLACEMENTS

8.1 Replace Reagent

When the supply of reagent runs out during an analysis, the instrument automatically stops and one of the messages below appears. At this time replace the reagent indicated.

Table 5-8-1: Reagent Messages

MESSAGE:	REPLACE:
Replace Reagent Container PK(1)	CELLPACK (PK-30L)
Replace Reagent Container PK(2)	
Replace Reagent Container PK(3)	
Replace Reagent Container FDO	STROMATOLYSER-FD (I) (FDO-200A)
Replace Reagent Container FDT	STROMATOLYSER-FD (II) (FDT-200A)
Replace Reagent Container FBA	STROMATOLYSER-FB (FBA-200A)
Replace Reagent Container SLS	SULFOLYSER (SLS-210)

(1) Verify that the new reagent container:
- is within the expiration date
- does not display any signs of contamination
- has been stored at room temperature.

CAUTION:
- Store reagents at a room temperature of 5°C to 30°C. Do not use reagent that has been thought to be frozen.
- Do not shake the reagent containers to prevent formation of micro bubbles.
- Place additional reagent cubes near the instrument prior to use to prevent micro bubbles formation.
- After breaking the seal, make sure that no dust, bacteria, or other contaminants make their way into the container.

(2) Remove the cap from the new reagent's container. Save the cap for future use.

(3) Loosen the cap of the empty reagent container, and pull the Cubitainer spout kit tubing straight out.

(4) Insert the spout kit tubing straight into the new reagent container, and tighten the cap.

CAUTION:
- Do not use your hands to touch tubing that comes in contact with reagents to prevent dust and other contaminants from adhering to the tubing. Before attaching tubing, wash off adhering contaminants with reagent.
- Be careful not to spill reagent. If reagent spills, immediately wipe it out with a damp tissue.

(5) Press [Replace Reagent] keypad in the root menu. New reagent will be primed to replenish reagent tubing and internal reservoir chamber. "Aspirate Reagent" is being displayed on the top line of the LCD. The error message disappears. When the priming is completed, "Ready" is displayed.

(6) Press [More] and [Mainte.] keypads in the root menu. Press the [Reagent] key from the Maintenance second menu.

(7) Press the [New Lot] keypad in the reagent second menu. The New Lot screen will appear.

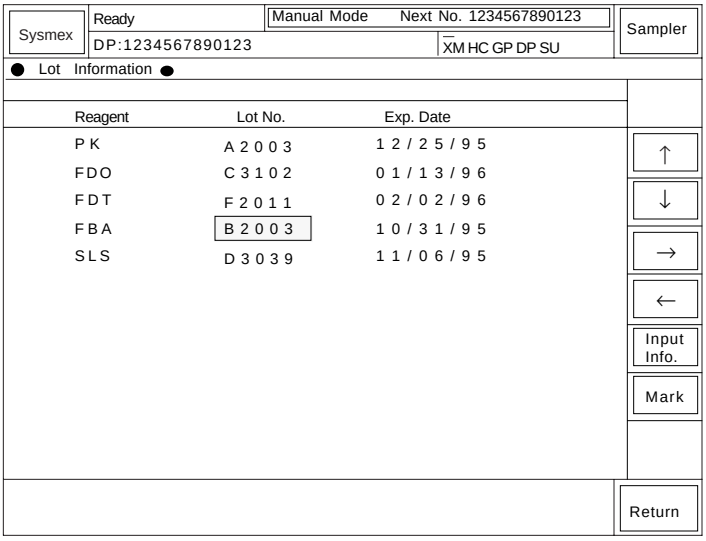


Figure 5-8-1: New Lot Screen

(8) Move the cursor to the reagent that was replaced using the [↑] and [↓] keys. Use the [←] and [→] keys to move the cursor to the lot number or expiration date column.

(9) Press [Input Info.] keypad.

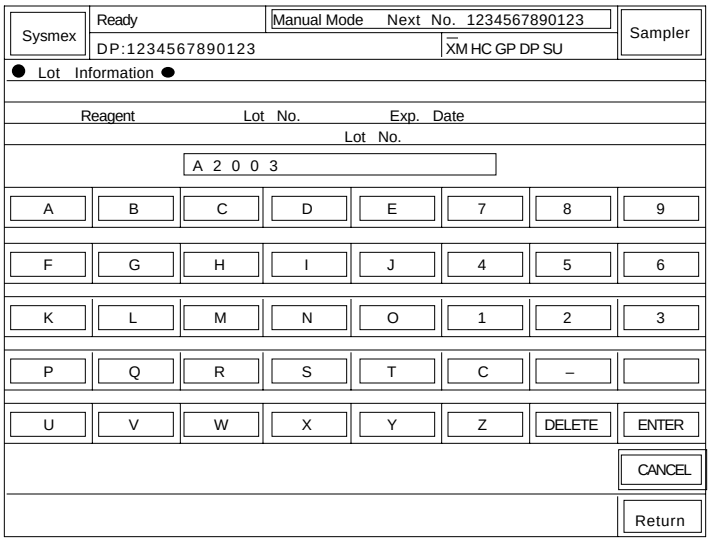


Figure 5-8-2: Lot Information Input Screen

(10) When the Lot No. is to be entered, the numeric and alphabet keys are displayed. Input the new lot number, and press [ENTER].

(11) When the expiration date is to be entered, the numeric keypads window will appear.

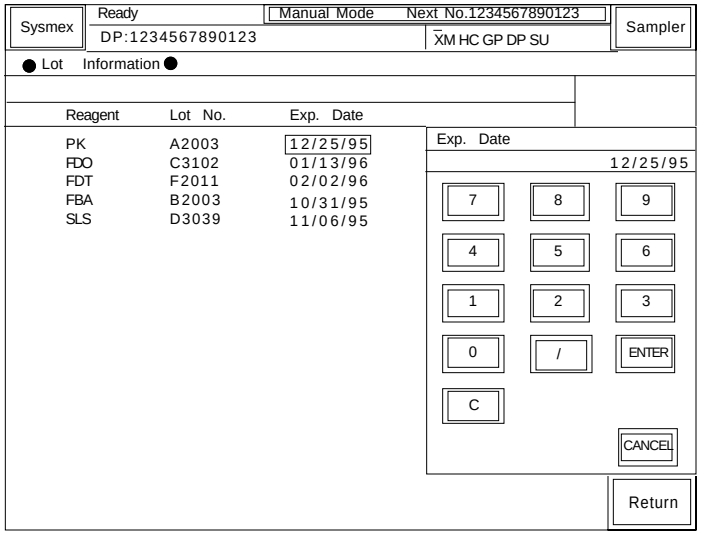


Figure 5-8-3: Expiration Date Input Screen

(12) Input the expiration date and press [ENTER]. The date format is in mm/dd/yy, dd/mm/yy or yy/mm/dd. The date should be either the date 2 months from today, or the expiration month printed on the reagent container with its last date, like 28/02/96 or 12/31/95, whichever comes first.

NOTE: The date format should conform to the system date setting.

(13) Press [Mark] key. A black box will appear on the left of reagent name. Pressing [Mark] again removes the box.

(14) Press the [Return] key to end the program. The reagent log of the reagent marked with a black box will be updated with the new lot information. The date and time when the reagent information is updated will automatically be recorded in the reagent log.

NOTE: Make sure to press [Mark] before pressing [Return] key. The reagent log will not be updated without a black box marking.

(15) Press [Auto Rinse] keypad in the root menu to execute a background check. Make sure that all background values are within the acceptable limits.

Table 5-8-2: Acceptable Background Limits

Parameters	Acceptable Limits
WBC/BASO Channel	0.1 [x $10^3/\mu L$]
DIFF Channel	0.1 [x $10^3/\mu L$]
RBC	0.02 [x $10^6/\mu L$]
HGB	0.1 [g/dL]
PLT	10 [x $10^3/\mu L$]

(16) Open the reagent replacement log by referring to *Section 8.1.1: Reagent Log* on the next page to verify the log is updated.

8.1.1 Reagent Log

This program is used to display the reagent replacement log, consisting of the lot numbers, open expiration date, replacement dates and times, of the last 100 replacements.

(1) Press the [Mainte.] key in the root menu. Press the [Reagent] key from the Maintenance second menu.

(2) Press the [Reagent Log] keypad in the Reagent submenu. The Reagent Log of the last 21 replacements will appear.

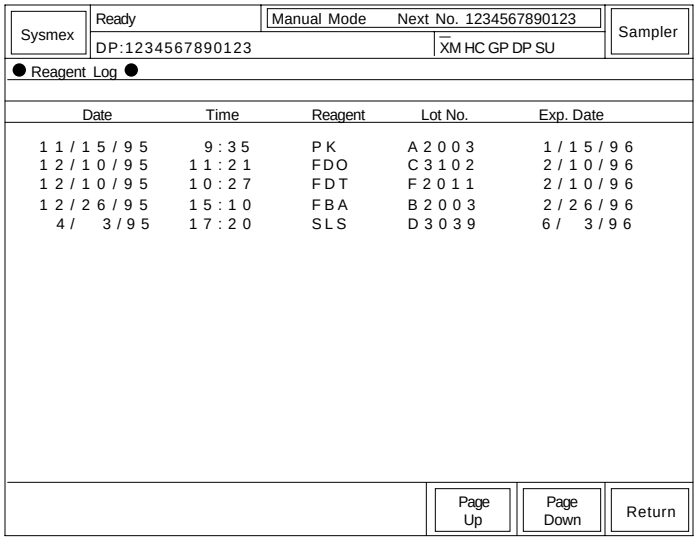


Figure 5-8-4: Reagent Log Screen

(3) Use the [Page Up] and [Page Down] keys to change the reagent log pages.

(4) Press [Return] to exit the program.

8.2 Replace the Piercer (Auto Sampler Unit)

Replace the piercer and reset the Piercer counter in the following procedure.

NOTE:
- After every 30 000 piercing operation cycles, the message "Replace Piercer" will be displayed at power ON.
- Piercer needle is a consumable item.

WARNING! The piercer should be considered potentially biohazardous. Do not handle the piercer without proper protective equipment. Wear gloves when replacing the piercer, and wash your hands with an antiseptic solution after completing the procedure.

CAUTION:
- When the number of the piercing operation exceeds 30 000, the needle point becomes worn out and it will increase the chance of injury and infection of biologically hazardous material if it breaks. It is recommended to replace the piercer needle when you get the message "Replace Piercer".
- The life time of the piercer needle depends on the rubber cap material, quality and usage conditions.

1. Removal

(1) Turn the Main Unit power switch OFF.

(2) Pull the CP cover straight up to remove it. Refer to Figure 5-8-5.

(3) Loosen the two piercing unit thumbscrews shown in Figure 5-8-6 so that the piercing unit is mobile.

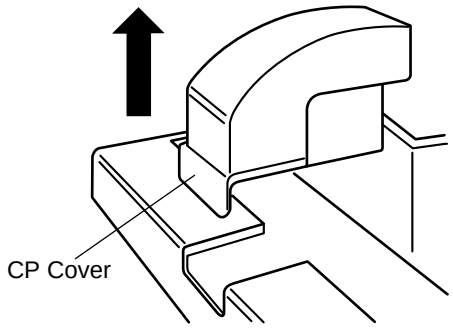


Figure 5-8-5: Remove CP Cover

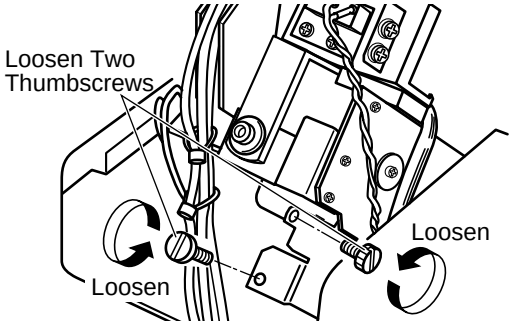


Figure 5-8-6: Loosen the Thumbscrews

(4) Pull up the mixer mechanism (Arrow ① in Figure 5-8-7). Install the holding metal for piercer replacement on the cylinder rod as shown in Figure 5-8-7 (Arrow ②). Make sure the mixer mechanism is secured.

(5) Push the mixer mechanism away from you. See Figure 5-8-8.

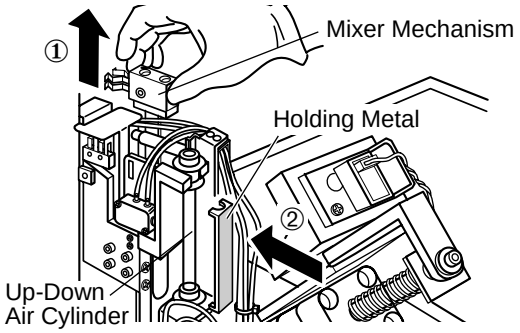


Figure 5-8-7: Set the Holding Metal

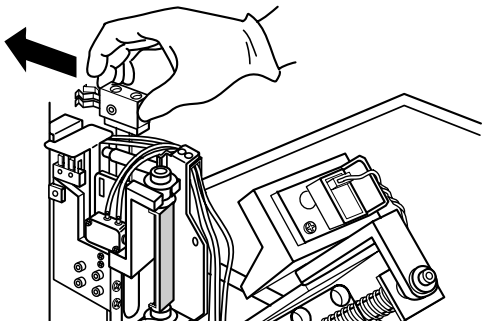


Figure 5-8-8: Push Mixer Mechanism

(6) Pull the piercing unit toward you (Arrow ① in Figures below), then lower the unit to lay down (Arrow ②).

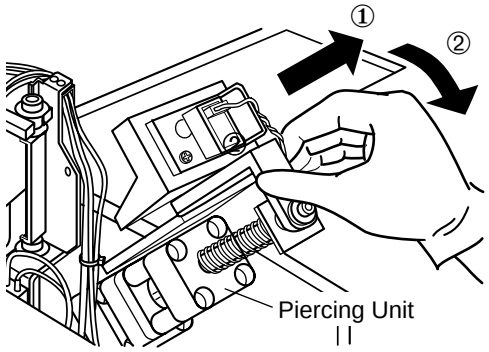


Figure 5-8-9: Pull the Piercing Unit

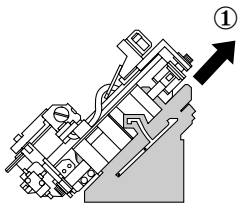


Figure 5-8-10: Pull the Piercing Unit (Cross Section View)

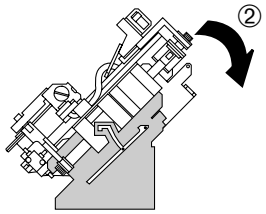


Figure 5-8-11: Lower the Piercing Unit (Cross Section View)

(7) When the piercing unit is horizontal, slide the unit away from you and lock it in place (Figure 5-8-12).

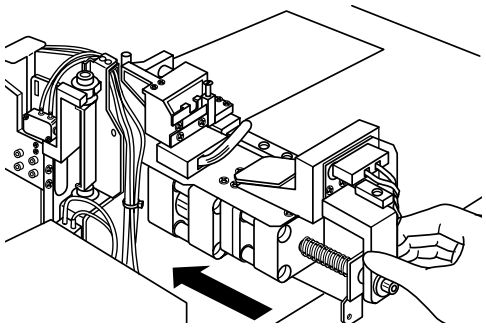


Figure 5-8-12: Slide the Unit to Lock

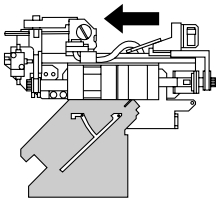


Figure 5-8-13: Slide the unit to lock (Cross Section View)

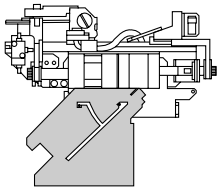


Figure 5-8-14: Unit has been locked (Cross Section View)

(8) Disconnect the three tubes shown in Figure 5-8-15.

CAUTION: Do not cut or bend the tubes.

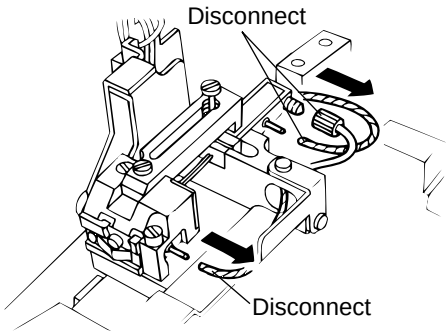


Figure 5-8-15: Disconnect the Tubes

(9) Unscrew the needle fixing screw with a screwdriver (see Figure 5-8-16). If the fixing screw is fixed in the fixing plate, the piercer needle is locked and never comes out.

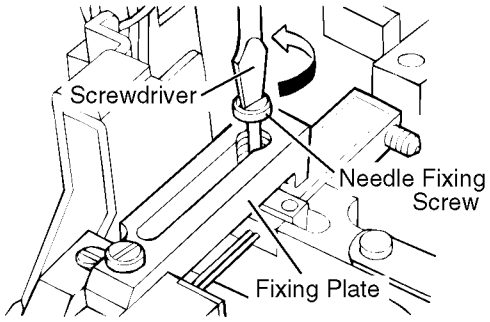
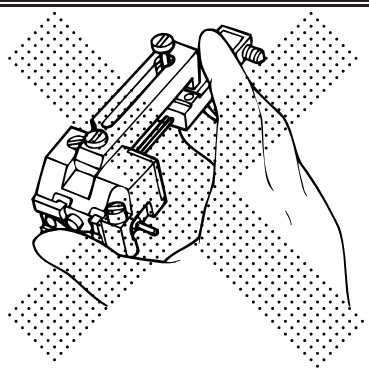


Figure 5-8-16: Lock the Piercer Needle

WARNING! If the piercing unit is removed without loosening the fixing screw, the piercer needle will accidentally come out from the rinse cup, which is dangerous. You must first loosen the fixing screw before removal.



(10) Loosen the two thumbscrews shown in Figure 5-8-17, and remove the piercer.

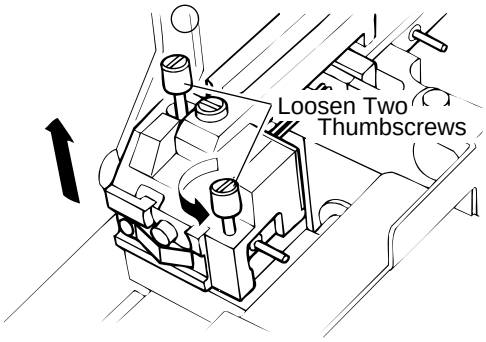


Figure 5-8-17: Loosen Two Thumbscrews

2. Installation

(1) Insert the new piercer, and retighten the thumbscrews (see Figure 5-8-18).

(2) Tighten the fixing screw until the piercer needle becomes free (see Figure 5-8-19).

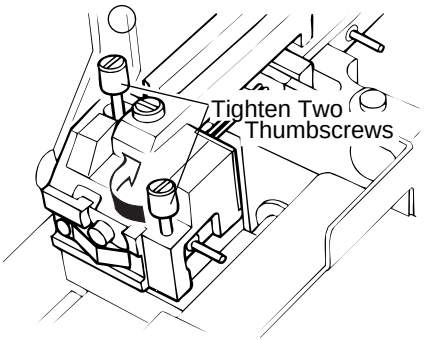


Figure 5-8-18:
Tighten the Thumbscrews

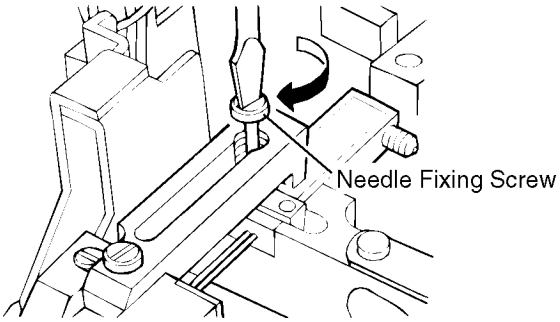
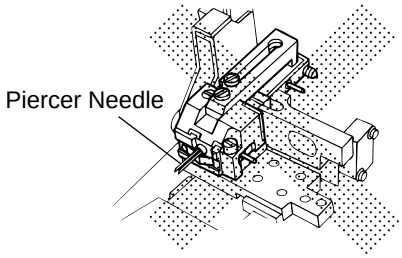


Figure 5-8-19:
Tighten the Fixing Screw

WARNING! After tightening the needle fixing screw, the piercer needle may be exposed.



(3) Reconnect the three tubes as shown in Figure 5-8-20.

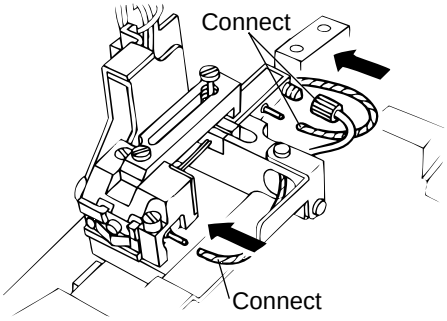


Figure 5-8-20: Reconnect the Tubes

(4) Return the piercing unit to its original position. The first step is to pull the unit toward you to release the lock (Arrow ① in Figure 5-8-21). Next, lift the unit and push it down to its original position (Arrows ② and ③).

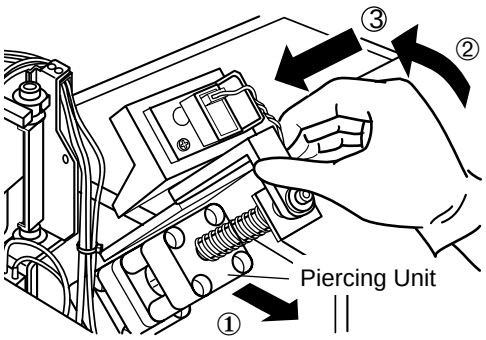


Figure 5-8-21: Set the Piercing Unit

CAUTION: Take care not to catch, pinch or bend the tubing when replacing the piercing unit.

(5) Remove the holding metal securing the mixing mechanism from the cylinder rod (Arrow ① in Figure 5-8-22). Then pull down the mixing mechanism (Arrow ②).

(6) Tighten the two piercing unit thumbscrews to secure the piercing unit (see Figure 5-8-23).

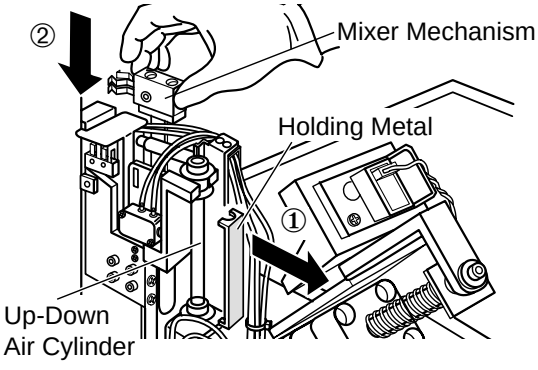


Figure 5-8-22: Remove the Holding Metal

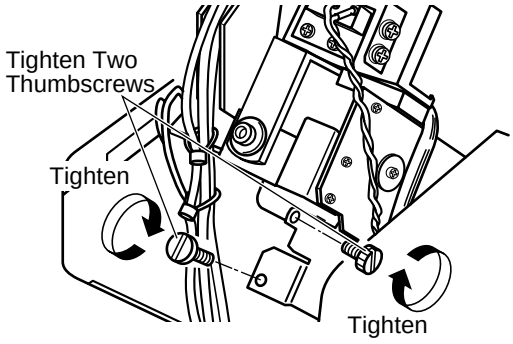


Figure 5-8-23: Tighten the Thumbscrews

(7) Reset the CP cover.

CAUTION: Take care not to pinch or bend the tubing when replacing the CP cover.

(8) Turn the power ON.

(9) Reset the piercer counter by referring to *Section 9* in this chapter.

NOTE: Make sure to reset the counter. If not reset, the message "Replace Piercer" will remain on the LCD.

(10) Record the replacement on the maintenance log.

8.3 Replace the Piercer (Manual CP Unit)

Replace the piercer every 30 000 piercing operation cycles.
When the number of the piercing operation reaches 30 000, the message "Replace Piercer" will be displayed on the LCD screen. Replace the piercer in the following procedure.

NOTE: Piercer needle is a consumable item.

WARNING! The piercer should be considered potentially biohazardous. Do not handle the piercer without proper protective equipment. Wear gloves when replacing the piercer, and wash your hands with an antiseptic solution after completing the procedure.

CAUTION:
- When the number of the piercing operation exceeds 30 000, the needle point becomes worn out and it will increase the chance of injury and infection of biologically hazardous material if it breaks. It is recommended to replace the piercer needle when you get the message "Replace Piercer".
- The life time of the piercer needle depends on the rubber cap material, quality and usage conditions.

1. Removal

(1) Turn the Main Unit power switch OFF.

(2) Pull the Manual CP Unit cover straight up to remove it. Refer to Figure 5-8-24.

(3) Open the tube lid (see Figure 5-8-25).

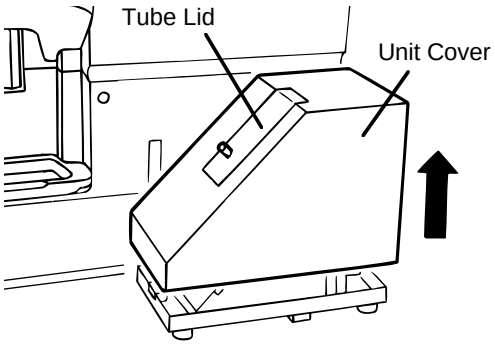


Figure 5-8-24: Remove the Unit Cover

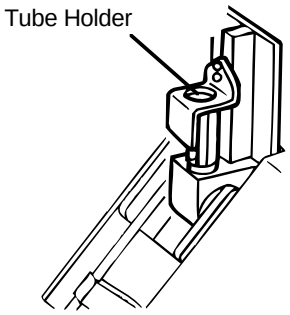


Figure 5-8-25: Open the Tube Lid

(4) Disconnect the three tubes (①, ② and ③) shown in Figure 5-8-26.

> **CAUTION:** Do not clamp or bend the tubes.

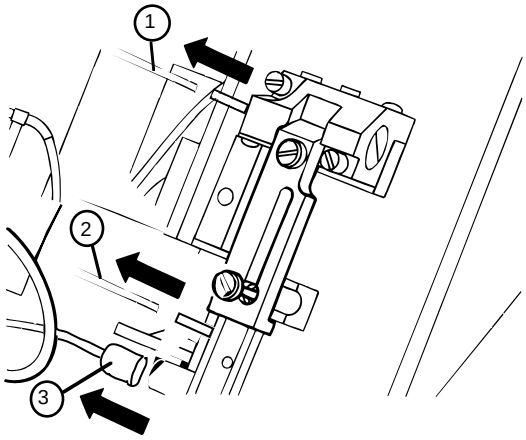


Figure 5-8-26: Disconnect the Tubes

(5) Unscrew the thumbscrew with a screwdriver (see Figure 5-8-27). If the thumbscrew is fixed in the fixing plate, the piercer needle is locked and never comes out.

(6) Loosen the two thumbscrews shown in Figure 5-8-28, and remove the piercer.

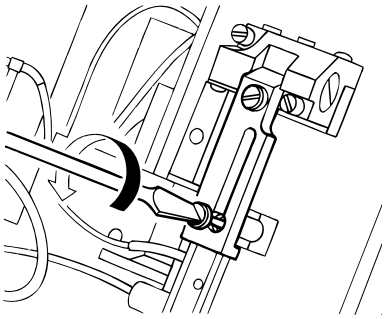


Figure 5-8-27: Lock the Piercer

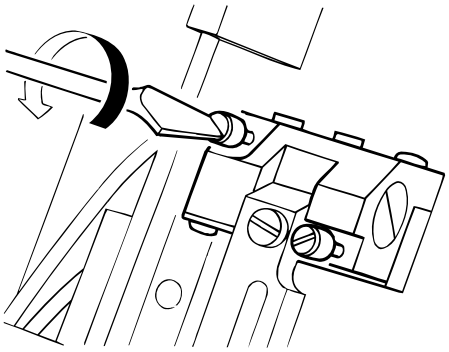


Figure 5-8-28: Loosen the Thumbscrews

2. Installation

(1) Insert the new piercer, and retighten the thumbscrews (see Figure 5-8-29).

(2) Tighten the thumbscrew until the piercer needle becomes free (see Figure 5-8-30).

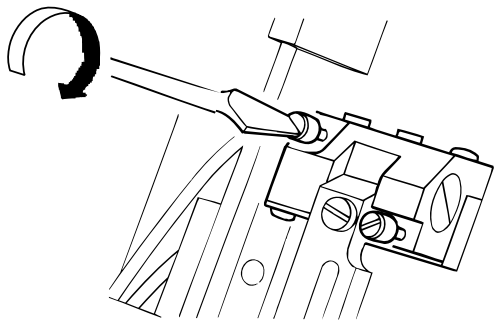


Figure 5-8-29: Tighten the Thumbscrews

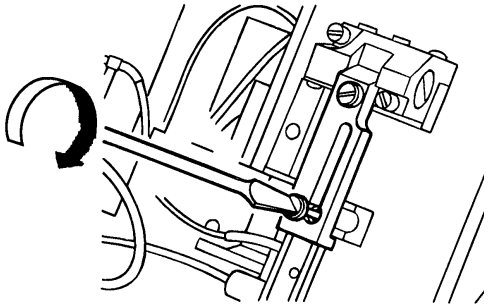
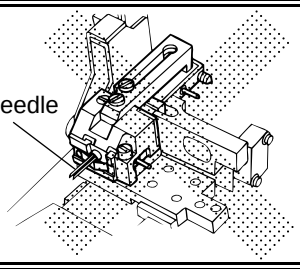


Figure 5-8-30: Release the Piercer Needle

WARNING! After tightening the needle fixing thumbscrew, the piercer needle may be exposed.



(3) Reconnect the three tubes (①, ② and ③) as shown in Figure 5-8-31.

(4) Reset the Manual CP cover.

CAUTION: Take care not to pinch or bend the tubing when replacing the cover.

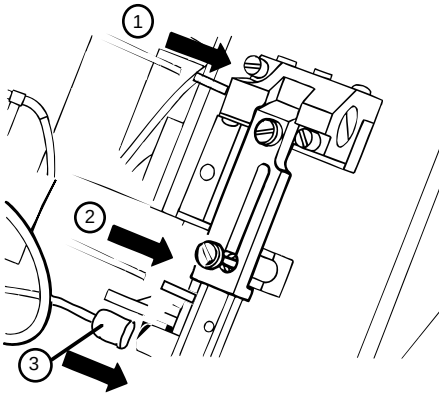


Figure 5-8-31: Reconnect the Tubes

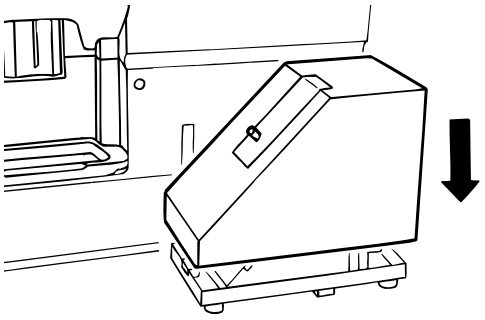


Figure 5-8-32: Set the Unit Cover

(5) Turn the power ON.

(6) Reset the piercer counter by referring to *Section 9* in this chapter.

NOTE:	Make sure to reset the counter. If not reset, the message "Replace Piercer" will remain on the LCD.

(7) Record the replacement on the maintenance check list.

8.4 Replace the Hand Clipper (Auto Sampler Unit)

When the hand clipper becomes deformed and cannot grasp the test tubes, replace it as follows.

WARNING! The hand clippers should be considered potentially biohazardous. Do not perform this procedure without proper protective equipment. Wear rubber gloves when replacing. Wash your hands with an antiseptic solution after completing the procedure.

(1) Turn OFF the power to the Main Unit.

(2) Pull the CP cover straight up to remove it. Refer to Figure 5-8-33.

(3) Loosen the two fixing screws to remove the hand clipper.

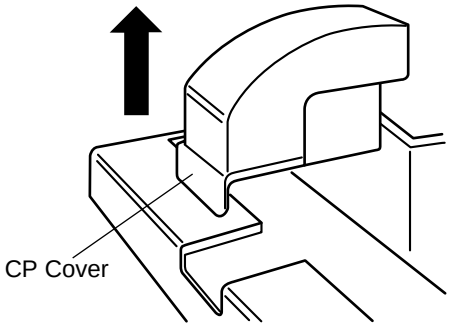


Figure 5-8-33: Remove CP Cover

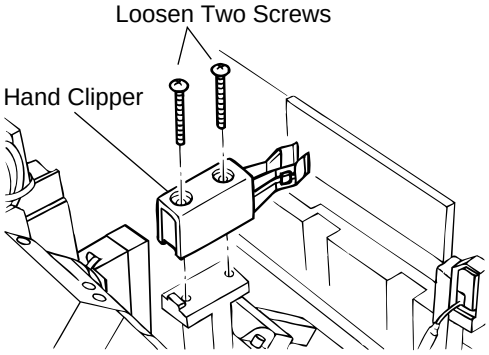


Figure 5-8-34: Loosen the Fixing Screws

(4) Install the new hand clipper, and tighten the fixing screws to secure it.

(5) Reset the CP cover and turn ON the power.

CAUTION: Take care not to pinch or bend the tubing when replacing the cover.

(6) Record the replacement on the maintenance log.

8.5 Replace the Rubber Plate No. 39 (Auto Sampler Unit)

When the test tubes start to slip from the hand clippers, replace the rubber plate as follows.

WARNING! The hand clippers should be considered potentially biohazardous. Do not perform this procedure without proper protective equipment. Wear rubber gloves when replacing. Wash your hands with an antiseptic solution after completing the procedure.

(1) Turn OFF the power to the Main Unit.

(2) Pull the CP cover straight up to remove it. See Figure 5-8-35.

(3) Remove the old rubber plate(s) from the hand clipper shown in Figure 5-8-36.

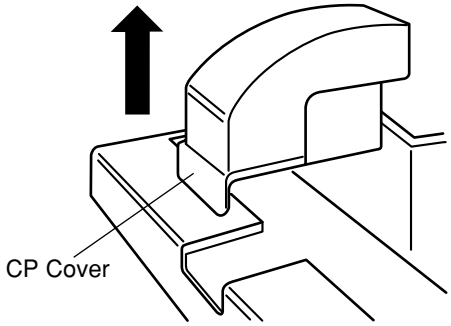


Figure 5-8-35: Remove CP Cover

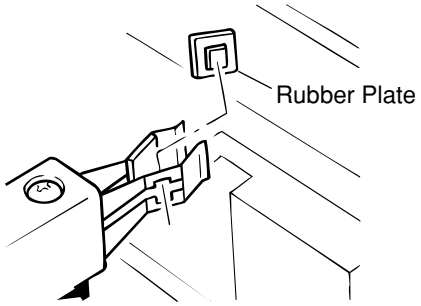


Figure 5-8-36: Rubber Plate No. 39

(4) Place a new Rubber Plate No. 39 (found in the supply parts) inside the hand.

(5) Reset the CP cover and turn ON the power.

CAUTION: Take care not to pinch or bend the tubing when replacing the cover.

(6) Record the replacement on the maintenance log.

8.6 Replace the Anti-Shock Rubber No. 49 (Auto Sampler Unit)

If an unusual vibration or noise is heard from the hand clipper while mixing a sample, replace the anti-shock rubber as follows.

WARNING! The hand clippers should be considered potentially biohazardous. Do not perform this procedure without proper protective equipment. Wear rubber gloves when replacing. Wash your hands with an antiseptic solution after completing the procedure.

(1) Turn OFF the power to the Main Unit.

(2) Pull the CP cover straight up to remove it. See Figure 5-8-37.

(3) Remove the old anti-shock rubber shown in Figure 5-8-38 when the hand clipper is tilted forward.

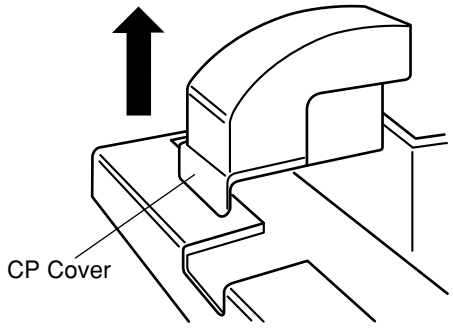


Figure 5-8-37: Remove CP Cover

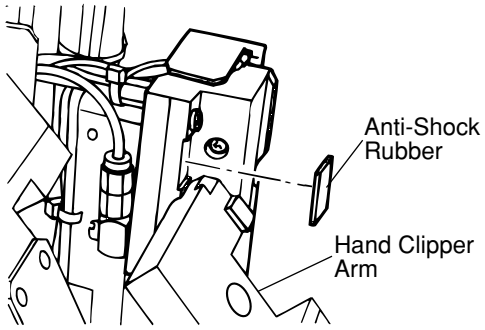


Figure 5-8-38: Anti-Shock Rubber No. 49 (View from the instrument right side)

(4) Use a lint-free tissue moistened with alcohol to wipe the area on which a new anti-shock rubber is placed.

CAUTION: The anti-shock rubber may be incorrectly positioned if any adhesive or oil remains, which causes errors and interrupts analysis.

(5) Place a new Anti-Shock Rubber No. 49 (found in the supply parts).

(6) Reset the CP cover and turn ON the power.

CAUTION: Take care not to pinch or bend the tubing when replacing the cover.

(7) Record the replacement on the maintenance check list.

8.7 Replace the Fuses

Overcurrent protection fuses are used in the Main Unit and Pneumatic Unit. Follow the procedure below to replace blown fuses.

> **WARNING!** To avoid risk of electrical shock, disconnect the power cord before replacing the fuses.

(1) Turn OFF the power to the Main Unit, and disconnect the power cord.

(2) Using a screwdriver, remove the fuse cap holders. Refer to the drawings below for the type of fuse holder.

<Main Unit Right Side> **<Pneumatic Unit Right Side>**

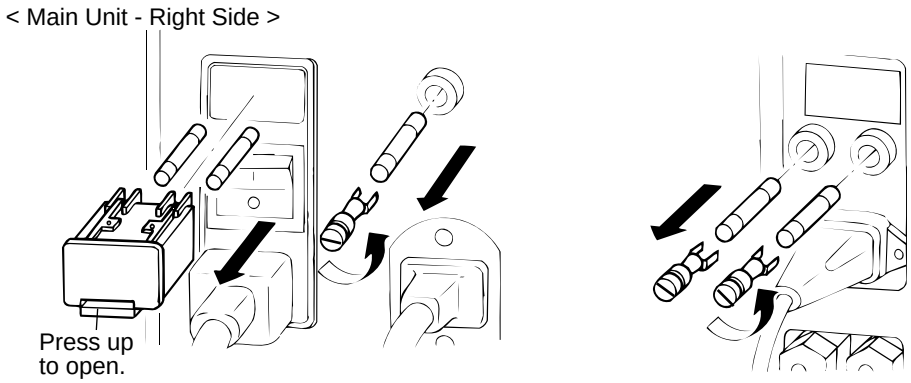


Figure 5-8-39: Replace the Fuses

(3) Replace the fuses; then reattach the fuse cap holders.

> **CAUTION:** For continued protection against risk of fire, replace only with a fuse of the specified type and current ratings.

Table 5-8-3: Main Unit Fuses

Specification	Part No.	Description	Fuse Type	Location
117 VAC	266-5108-7	Fuse 250V8A ST4-8A-N1	Time Lag	Right Side
220/240 VAC	266-5297-4	Fuse 250V4A No.19195	Time Lag	Right Side
117 VAC	266-5106-0	Fuse 250V6.3A ST4-6.3A-N1	Time Lag	Right Side
220/240 VAC	266-5293-0	Fuse 250V3.15A No.19195	Time Lag	Right Side

Table 5-8-4: Pneumatic Unit Fuses

Specification	Part No.	Description	Fuse Type	Location
117 VAC	266-5011-3	Fuse 250V4A ST4-4A-N1	Time Lag	Right Side
220/240 VAC	266-5292-6	Fuse 250V2A No.19195	Time Lag	Right Side

(4) Connect the power cord and turn ON the power.

(5) Record the replacement on the maintenance log.

8.8 Replace the Belt No. 6

If the motor belt of the Reaction Chamber Mixing Motor is cut, the message "Mixing Motor Speed Error" will appear. Replace the Belt No. 6 as follows.

(1) Turn OFF the power to the Main Unit.

(2) Open the front cover and set the stop bar in position.

> **WARNING!** When working with the front cover open, make sure that the stop bar is in place to avoid accidental closure.

(3) Disconnect the connector to the Mixing Motor shown in figure below.

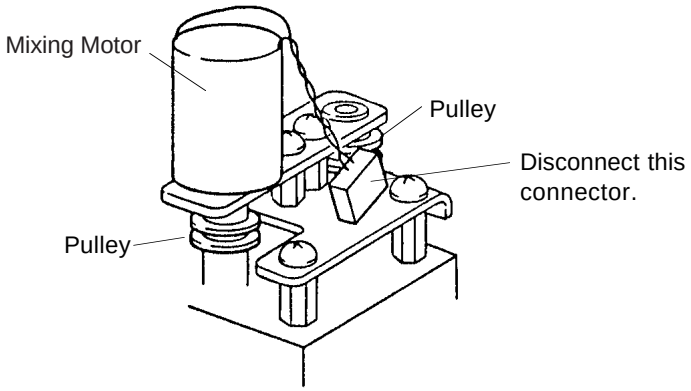


Figure 5-8-40: Mixing Motor

(4) Remove the Belt No. 6.

(5) Set a new Belt No. 6 (found in the supply parts) on the pulleys. Make sure the belt is not twisted. See the figure below.

CAUTION: Take care not to damage the belt by the edge or corner of metal parts.

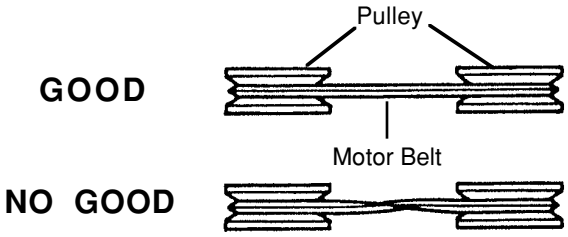


Figure 5-8-41: Set Motor Belt

(6) Connect the connectors.

(7) Turn ON the power. Visually check the motor operation.

(8) Release the stop bar and close the front cover.

(9) Press [Mainte.] keypad in the root menu, then press [Test].

(10) Press [Mixing Motor] key from the Test submenu.

(11) Press the Start Switch to start the mixing motor test program and verify that the rotation speed is stable within the normal range of 1600 - 2000 rpm.

NOTE: Refer to *Chapter 8, Section 3.3: Test Motor* for the test program.

(12) Record the replacement on the maintenance log.

9. RESET THE COUNTER

This program is for resetting the counters, which indicate the number of operations each unit has performed.

(1) Press the [Mainte.] key from the root menu. The Maintenance second menu will be displayed.

> **NOTE:** If the [Mainte.] key is not displayed on the LCD, press [More] to change the displayed root menus.

Figure 5-9-1: Maintenance Second Menu

(2) Press [Service Data] key from the Maintenance second menu. The WBC Service Data will appear.

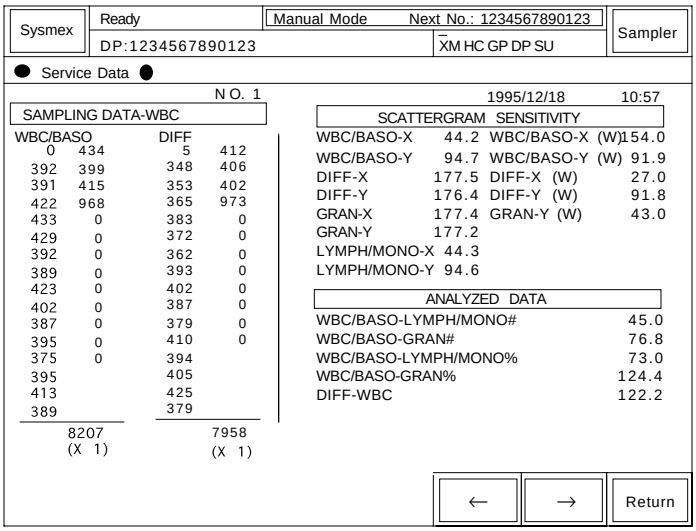


Figure 5-9-2: Service Data - WBC Screen

(3) Press the [←] key. The Counter screen containing the number of operations performed by each unit will appear on the LCD.

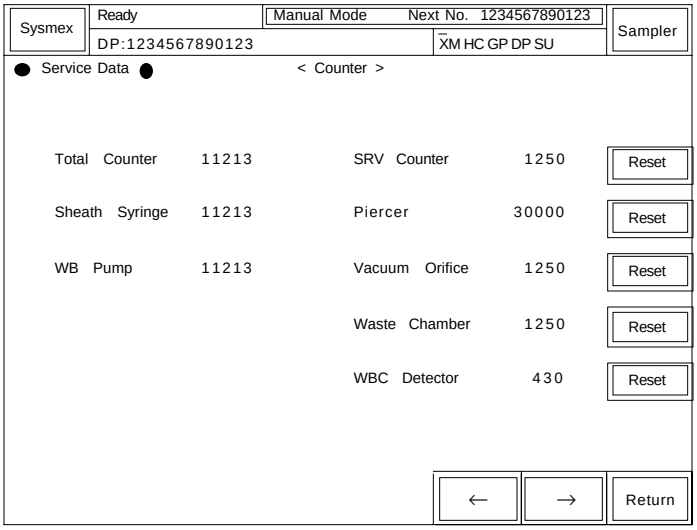


Figure 5-9-3: Counters Screen

(4) Press the [Reset] key on the right of the unit to reset the operation count to zero (0).

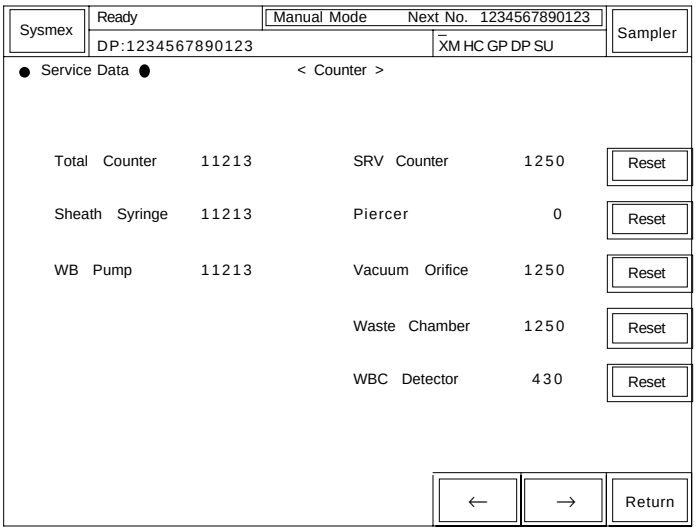


Figure 5-9-4: Reset Counter Screen (Reset the Piercer Counter)

(5) Press [Return] key. The confirmation message window will appear.

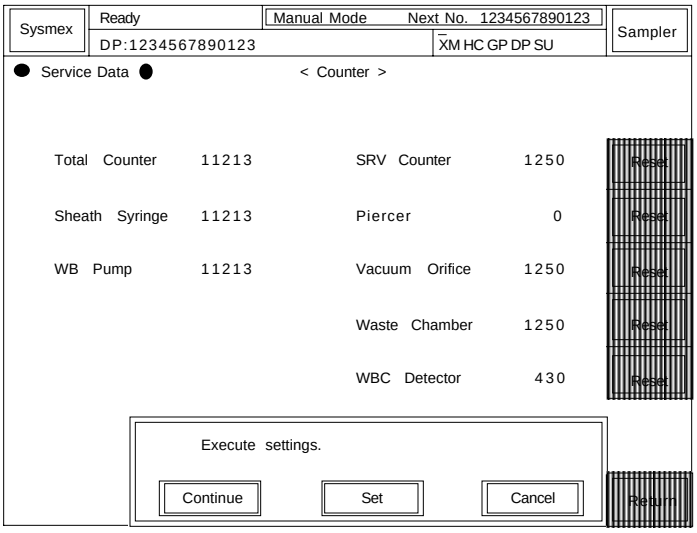


Figure 5-9-5: Reset Counters Confirmation Screen

(6) Press [Continue] to return to the Counter screen.
Press [Set] to reset the counter.
Press [Cancel] to cancel the counter reset and exit the Service Data program.

10. FORMAT FD

This program is for formatting a 3.5 inch 2HD type floppy disk to use on the SF-3000.

(1) Press the [Mainte.] key from the root menu. The Maintenance second menu will be displayed. Press [More] to alter the displayed Maintenance second menu.

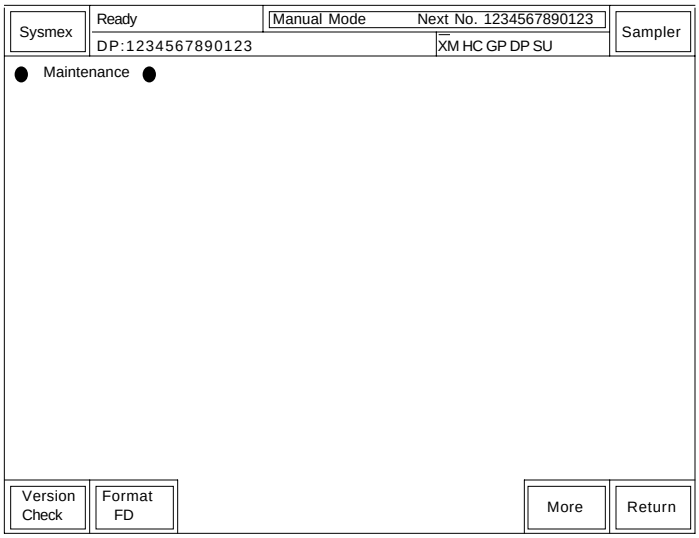


Figure 5-10-1: Maintenance Second Menu (Altered)

(2) Press [Format FD] key from the Maintenance second menu. The Format FD screen will appear.

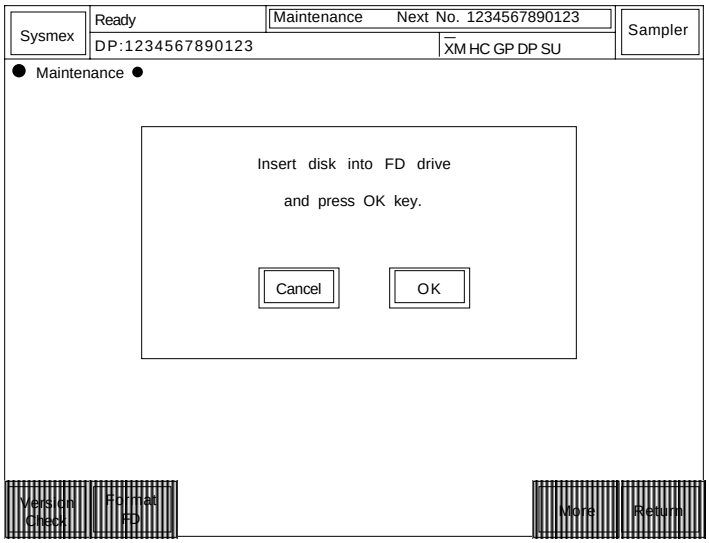


Figure 5-10-2: Format FD Screen

(3) Insert a 3.5 inch floppy disk into the floppy disk drive on the right side of the Main Unit, and press [OK]. The confirmation message will appear.

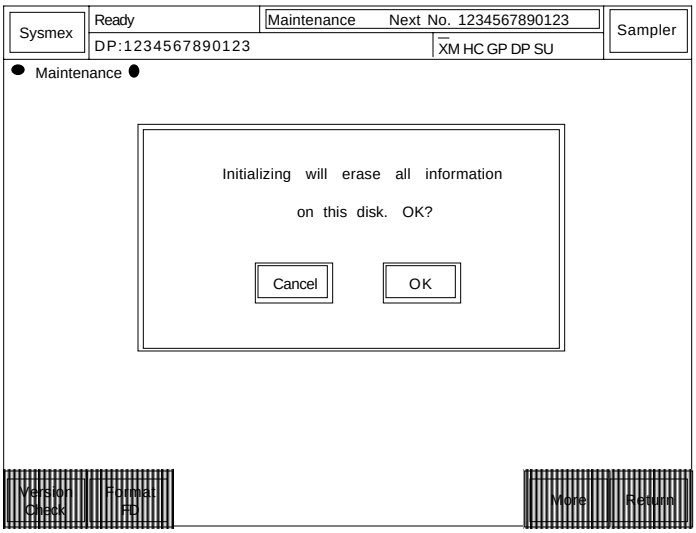


Figure 5-10-3: Format FD Confirmation Window

(4) The floppy disk is formatted in 1.44 MB format. It takes approx. one minute and 30 seconds to complete.
While formatting the floppy disk, the message "Formatting disk ..." will be displayed.

(5) When the formatting is completed, the message window shown below will appear.

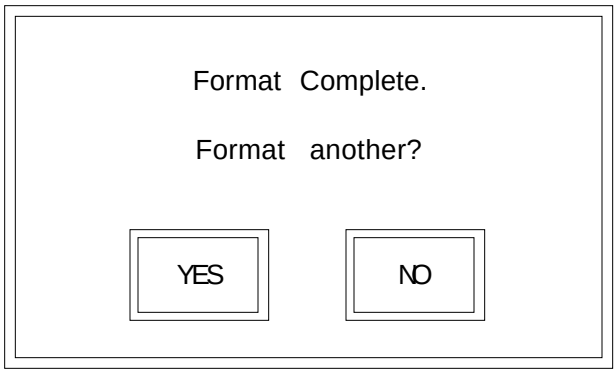


Figure 5-10-4: Format Complete Message Window

(6) Press [Yes] to format another disk, or press [No] to end the program.

(7) When the disk formatting fails, "Cannot format this disk. Format another?" message appears. Press [Yes] to retry formatting, or press [No] to end the program.

11. SUPPLIES AND REPLACEMENT PARTS LISTING

1. Supplies

Part Number	Description	Volume
884-0871-1	CELLPACK (PK-30L)	20 L
944-0431-1	STROMATOLYSER-FD (I) (FDO-200A)	5 L
944-0791-1	STROMATOLYSER-FD (II) (FDT-200A)	500 mL
944-0461-3	STROMATOLYSER-FB (FBA-200A)	5 L
834-0162-1	CELLCLEAN (CL-50)	50 mL
904-1151-1	SULFOLYSER (SLS-210)	500 mL

2. Replacement Parts

Part Number	Description	Reference Section
366-1229-0	Holder No. 56 (14 mm-Dia Tubes)	Chapter 2, Section 4.3
366-1231-8	Holder No. 58 (13 mm-Dia Tubes)	Chapter 2, Section 4.3
833-3315-1	Sample Rack (6/Pack) (C-5)	Chapter 2, Section 4.3
933-3601-9	Transducer Brush No. 1	Chapter 5, Section 7.4
971-0591-5	Piercer Set No. 3	Chapter 5, Section 8.2, 8.3
923-8101-4	Hand Clipper S#4 Assy (C1/Pier)	Chapter 5, Section 8.4
368-0079-6	Rubber Plate No. 39	Chapter 5, Section 8.5
368-0196-5	Anti-Shock Rubber No. 49	Chapter 5, Section 8.6
266-5108-7	Fuse 250V8A ST4-8A-N1	Chapter 5, Section 8.7
266-5297-4	Fuse 250V4A No.19195	Chapter 5, Section 8.7
266-5106-0	Fuse 250V6.3A ST4-6.3A-N1	Chapter 5, Section 8.7
266-5293-0	Fuse 250V3.15A No.19195	Chapter 5, Section 8.7
266-5011-3	Fuse 250V4A ST4-4A-N1	Chapter 5, Section 8.7
266-5292-6	Fuse 250V2A No.19195	Chapter 5, Section 8.7
342-2626-4	Belt No. 6	Chapter 5, Section 8.8

CHAPTER 6 QUALITY CONTROL

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1. INTRODUCTION

Quality Control (QC) checks the accuracy of sample analysis data from day to day.

Specifically, QC consists of checking that the followings are satisfactory: (a) accuracy of analysis results (i.e., whether the values obtained are correct) and (b) precision (i.e., reproducibility -- whether the same values are obtained when analysis is repeated on a sample).

Two types of QC are used in the SF-3000: Individual QC, which is performed on individual samples, and Statistical QC, which uses statistical methods.

- **Individual QC** : Refers to the function that monitors samples individually. Aspects monitored include: blood aspiration sensor, reagent sufficiency, electrical noise, and the plateau portions of cell size distribution curves (histograms).

- **Statistical QC** : Refers to statistical calculations performed on sample analysis and control blood analysis data. These calculations are carried out by the QC Program.

• Statistical QC Program

The QC Program's main function is to provide highly reliable and accurate data by running control blood material. However, to maintain the reliability of analyzed data, constant monitoring by the operator of daily and hourly changes in analysis precision is required.

Note that the QC program must be started after the instrument is correctly calibrated. If it is not properly calibrated, monitoring of daily and hourly changes in system accuracy will be pointless, no matter how thorough the QC program is carried out.

Calibration is carried out using the calibration programs. RBC and other blood cell counts are controlled in the same way as in previous Sysmex models, by means of checking the data values on control blood specified by Sysmex.

This chapter explains: QC charts, how to set $\overline{X}$ /L-J and $\overline{X}$ M monitoring, file deletion, backup, and certain other items.

1.1 Types of QC Method

The SF-3000 QC program provides two types of control methods:

- **Commercial Control ($\overline{X}$ or L-J)**

$\overline{X}$ Control : Performs two consecutive analyses of control blood, and takes the mean (average) value of the two analyses as one control data.

L-J (Levy-Jennings) Control : Takes the data from a single analysis of control blood as the control data. This control method can also monitor daily changes in sampler analysis.

- **Patient Data Analysis ($\overline{X}$ M)**

: Calculates the weighted moving average of batches of 20 patient samples (or a user-selected number), and takes the resultant value as a control data.

1.2 QC Parameters To Be Monitored

To derive full benefit from the control application, it is best to use $\overline{X}$ or L-J Control in conjunction with $\overline{X}$ M Control. For example, if an abnormality occurs in $\overline{X}$ M Control, the operator should check the $\overline{X}$ M control chart, and execute $\overline{X}$ Control or L-J Control to verify the control data results of $\overline{X}$ or L-J Control.

In addition to the 23 QC parameters normally displayed on the screen, the SF-3000 also has 5 other sensitivity-related parameters for a total of 28 parameters.

Table 6-1: QC Parameters

Monitored Parameters	
8 CBC Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT
10 WBC Classification Parameters	NEUT%, LYMPH%, MONO%, EO%, BASO%, NEUT#, LYMPH#, MONO#, EO#, BASO#
5 Cell Size Analysis Parameters	RDW-SD, RDW-CV, PDW, MPV, P-LCR
5 Sensitivity-Related Parameters	GRAN-X, GRAN-Y, WBC/BA-X, WBC/BA-Y, GRAN-Y (W)

NOTE: *Customers in the United States:* Platelet Distribution Width (PDW) and Platelet Large Cell Ratio (P-LCR) parameters have not been approved for reporting by the Food & Drug Administration (FDA). The obtained values should be excluded from all print forms until reporting approval has been obtained. See *Chapter 11* for information on excluding these values.

2. DELETE FILE

To use the files for new lots of control material or to change the control material level (levels are: Normal, Abnormal Low and Abnormal High), all existing data should be deleted from the memory of the particular QC file. The QC -- Delete Files program can be used to delete any or all of the data from $\overline{X}$ /L-J files (File Nos. 1-12) and/or the $\overline{X}$ M file.

> **NOTE:** Individual control data results can also be deleted by selecting [Delete] - [Plot] from the submenu, and using the cursor to specify the exact control data results to be deleted.

(1) Press [QC] keypad in the root menu. QC second menu will be displayed.

(2) From the QC submenu, select [Delete]. The password entry screen will appear. Input the password and press [ENTER].

(3) From the Delete submenu, press [File]. A list of all the files will appear on the Delete File screen.

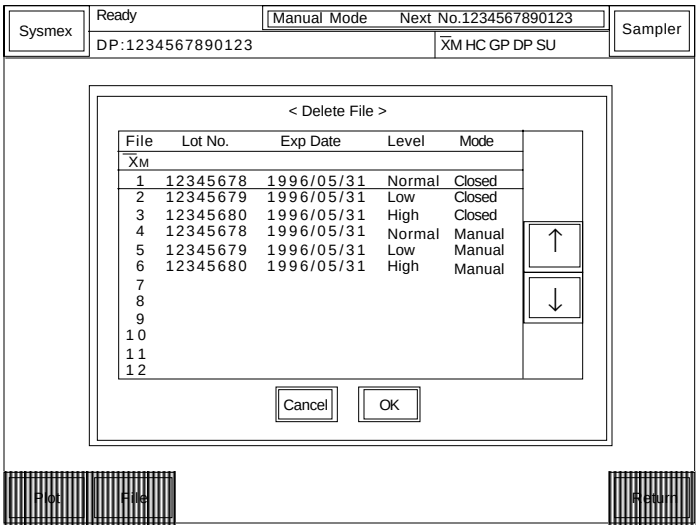


Figure 6-1: Delete File Selection Screen

(4) Using the [↑] and [↓] keys, select the file to be deleted.

(5) Press [OK]. The QC chart of the selected QC file with deletion confirmation message will appear.

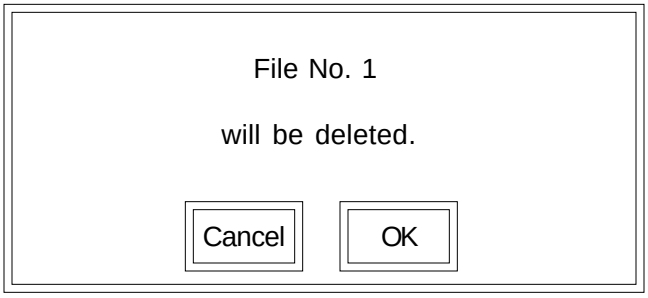


Figure 6-2: Delete Confirmation Message

Press [OK] to delete the specified file and end the program.
Press [Cancel] to cancel the deletion and end the program.

3. SYSTEM SETTINGS

To execute the QC Program, you must first enter the following and set the type of control method ($\overline{X}$ Control or L-J Control) and limit display method.

(1) Press [QC] in the root menu.

(2) Select [Settings] from the QC second menu. The Settings submenu will appear.

NOTE: If the [Settings] keypad is not displayed on the LCD, press [More] to change the displayed menus.

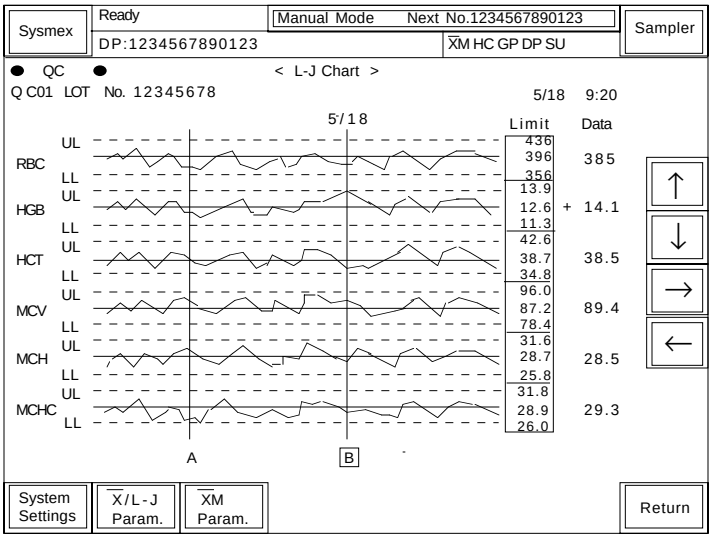


Figure 6-3: QC Settings Submenu

(3) Select [System Settings] from the submenu.

(4) The password entry screen will appear. Input the password and press [ENTER]. The System Settings screen will appear as shown below, and the current Control Method and Limit Display settings will be displayed.

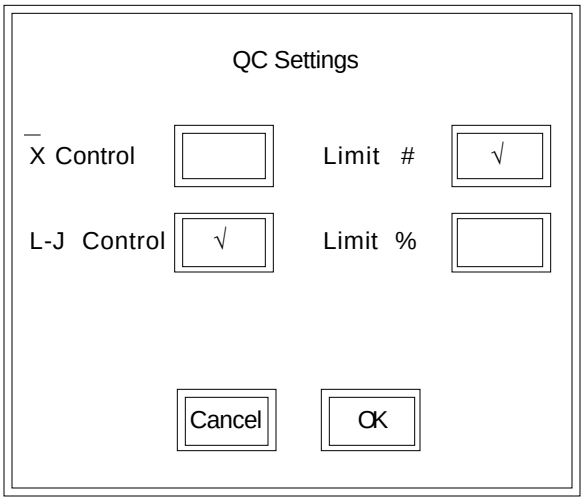


Figure 6-4: System Settings Screen

(5) Press the box on the right of the desired setting keypad for each item. A check mark "√" is placed in the box when selected.

- Control Method
  - $\overline{X}$ Control : This method performs two consecutive analyses of control blood, and takes the mean (average) value of the two analyses as one control data.
  - L-J Control : This method takes the data from a single analysis of control blood as the control data.

- Limit Display
  - Limit # : Limit (relative to TARGET) is calculated and displayed as an absolute value (SD).
  - Limit % : Limit (relative to TARGET) is calculated and displayed as a proportion (CV).

(6) Press [OK] to execute the new settings. The QC Setting window disappears. Press [Cancel] to cancel the new settings. The QC Setting window disappears.

NOTE: When setting the system items, either $\overline{X}$ Control or L-J Control must be selected, and this setting should not be changed until one lot of the control blood has expired. Changing from $\overline{X}$ Control to L-J Control or vice-versa on a daily basis should not be done.

4. QC PARAMETER SELECTION

4.1 Selecting QC Parameter ($\overline{X}$ /L-J Control)

Use this program to exclude unnecessary (non-monitored) parameters from $\overline{X}$ /L-J QC analysis.

(1) Press [QC] and [Settings] to select QC system setting program. The QC Settings submenu will appear.

(2) Press [$\overline{X}$ /L-J Param.] keypad. The password entry screen will appear.

(3) Input the password and press [ENTER]. The $\overline{X}$ /L-J parameters setting window will appear as shown below.

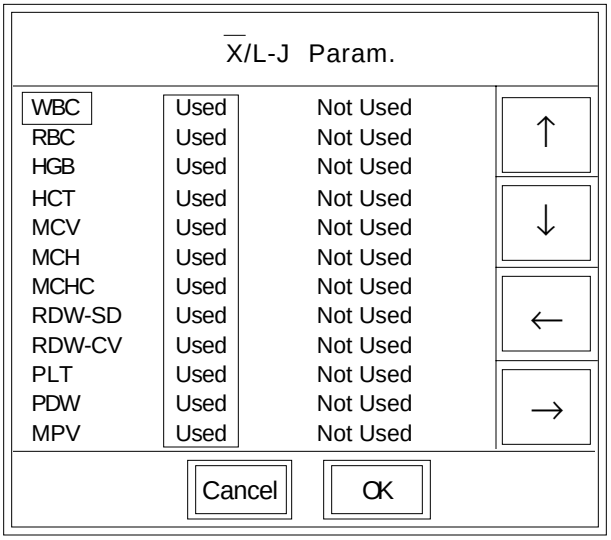


Figure 6-5: $\overline{X}$ /L-J Parameters Setting Window

(4) Use the [↑] and [↓] keys to specify a parameter. The selected parameter is displayed with green back-light.

(5) Use the [←] and [→] keys to specify "Used" (if the parameter is to be included in QC analysis) or "Not Used" (if the parameter is to be excluded from QC analysis). The selected setting is displayed in reverse video.

(6) Pressing [OK] key executes the new settings and the $\overline{X}$ /L-J parameter setting window will disappear.
Pressing [Cancel] key cancels the new settings and the $\overline{X}$ /L-J parameter setting window will disappear.

NOTE:
- Parameters specified as "Not Used" will not be plotted on the QC charts.
- Even though parameters are specified as "Not Used", the instrument will still perform analysis on them. They are just excluded from being plotted on the QC chart. If the operator changes "Not Used" parameter to a "Used" parameter, all previously excluded control data will be included on the QC chart.

4.2 Selecting QC Parameter ($\overline{X}$ M Control)

Use this program to exclude unnecessary (non-monitored) parameters from $\overline{X}$ M QC analysis.

(1) Press [QC] and [Settings] to select QC system setting program. The QC Settings submenu will appear.

(2) Press [$\overline{X}$ M Param.] keypad. The password entry screen will appear.

(3) Input the password and press [ENTER]. The $\overline{X}$ M parameters setting window will appear as shown below.

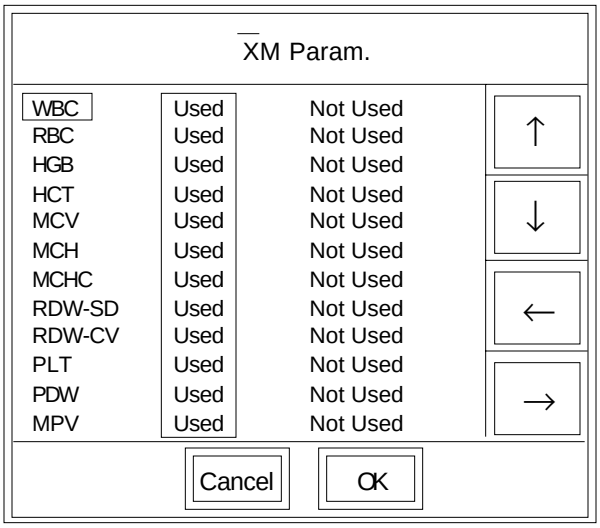


Figure 6-6: $\overline{X}$ M Parameters Setting Window

(4) Use the [↑] and [↓] keys to specify a parameter. The selected parameter is displayed with green back-light.

(5) Use the [←] and [→] keys to specify "Used" (if the parameter is to be included in QC analysis) or "Not Used" (if the parameter is to be excluded from QC analysis). The selected setting is displayed in reverse video.

(6) Pressing [OK] key executes the new settings and the $\overline{X}$ M parameter setting window will disappear.
Pressing [Cancel] key cancels the new settings and the $\overline{X}$ M parameter setting window will disappear.

NOTE:
- Parameters specified as "Not Used" will not be plotted on the QC charts.
- Even though parameters are specified as "Not Used", the instrument will still perform analysis on them. They are just excluded from being plotted on the QC chart. If the operator changes "Not Used" parameter to a "Used" parameter, all previously excluded control data will be included on the QC chart.

5. SETTING $\overline{X}$ M CONTROL

How to start/stop $\overline{X}$ M Control (which uses patient samples), and how to set the number of samples in the batch to be used as data for $\overline{X}$ M Control computation are explained below.
The presence or absence of "$\overline{X}$ M" in the System Status display informs the operator that $\overline{X}$ M Control is in start (activated) or stop (inactivated) mode. As soon as patient blood analysis starts, $\overline{X}$ M Control is activated automatically and performs quality control of specified number of samples in every batch. The data for each batch is stored in the $\overline{X}$ M Control File. The default number of samples per batch is 20, but can be changed to any number between 1 and 999.

5.1 Executing the $\overline{X}$ M Control Settings Program

(1) Press [QC] to display QC second menu.

(2) Press [$\overline{X}$ M Start/Stop] keypad from the second menu. The password entry screen will appear.

(3) Input the password and press [ENTER]. The $\overline{X}$ M setting window will appear, and the current number of samples per batch will be displayed as below.

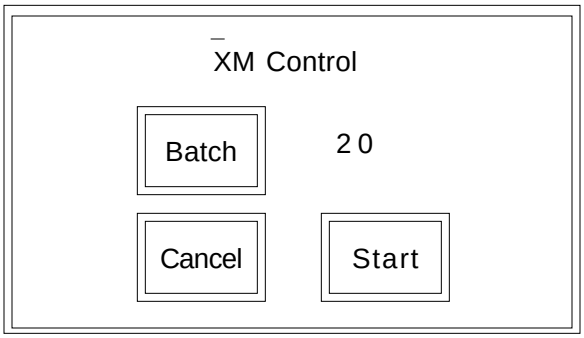


Figure 6-7: $\overline{X}$ M Control Settings Window

(4) Pressing [Batch] keypad displays the numeric keypads to specify the number of samples in a batch.
Use the numeric keys to enter the sample number and press [ENTER]. Pressing [CANCEL] cancels the sample number setting without changing the number.

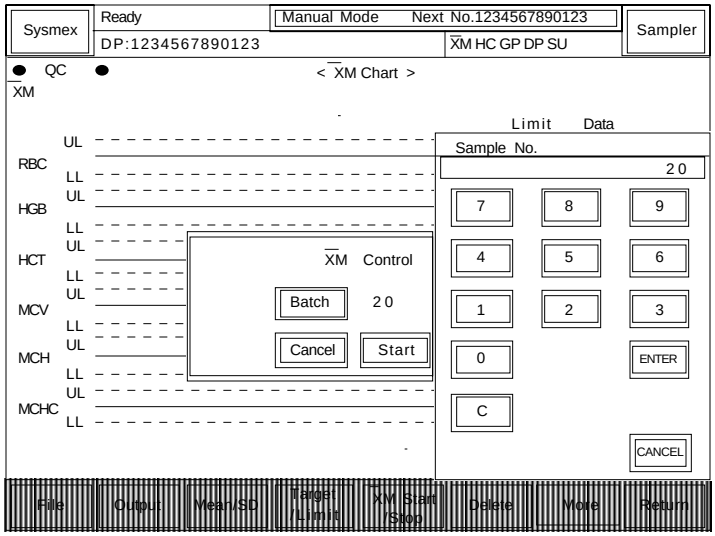


Figure 6-8: Sample No. Settings Window

(5) Press [Start] key in the $\overline{X}$M Settings window to start $\overline{X}$M Control. Pressing [Cancel] cancels the settings and the setting window will close.
When the $\overline{X}$M Control is started, "$\overline{X}$M" will be displayed in the System Status area in the top line of the LCD.

(6) To stop the $\overline{X}$M Control, press [$\overline{X}$M Start/Stop] keypad. The $\overline{X}$M Control window as shown below appears.

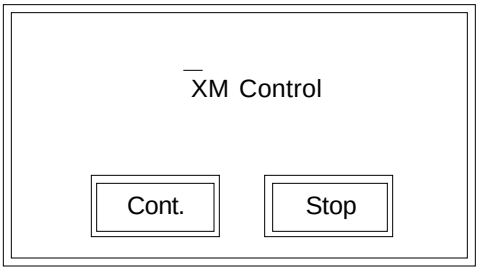


Figure 6-9: $\overline{X}$M Control Window

(7) Press the [Stop] key. This stops the $\overline{X}$ M Control and "$\overline{X}$ M" in the System Status area disappears.

NOTE: If several samples that clearly are from a different population are run in succession, the $\overline{X}$ M Control will judge as an abnormality to be present. In this case, set $\overline{X}$ M to "Stop", so that these samples will not be included in $\overline{X}$ M computation.

6. TARGET/LIMIT

This is used to set the QC Target, Limit# (%) values and control blood information manually or by down loading from a floppy disk (FD). Additionally, all the current QC file target and limit# (%) values are displayed for checking.

6.1 Display

Currently memorized $\overline{X}$ /L-J file lot Nos., expiration dates, and targets/limit# (%) are displayed in this reference list. To register targets, limit# (%) and control blood information, the file name must be specified here beforehand.

(1) Press [QC] to display QC second menu.

(2) Press [Target/Limit] keypad from the second menu. The first page of QC File Information List will be displayed.

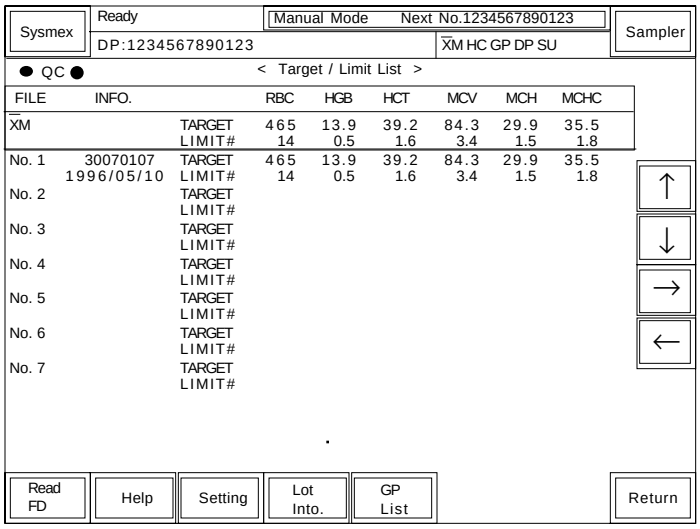
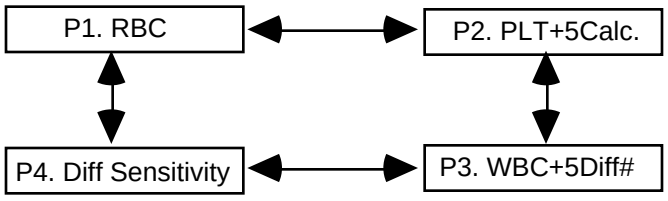


Figure 6-10: QC File Information Screen (P1: RBC)

(3) Use the [↑] and [↓] keys to select a file.

NOTE: Pressing the [↓] key when the cursor has reached the bottom of the screen will make the display to scroll up by one file number. (The cursor will appear at the bottom of the screen.) However, if the cursor is on File No. 12, no upward scrolling will occur.
Pressing the [↑] key when the cursor has reached the top of the screen will make the display to scroll down by one file number. (The cursor will appear at the top of the screen.) However, if the cursor is on $\overline{X}$ M, no downward scrolling will occur.

(4) The display consists of 4 pages. Use the [←] and [→] keys to change pages.



QC File Display Items	
P1. RBC	RBC, HGB, HCT, MCV, MCH, MCHC
P2. PLT+5Calc.	RDW-SD, RDW-CV, PLT, PDW, MPV, P-LCR
P3. WBC+5DIFF#	WBC, NEUT#, LYMPH#, MONO#, EO#, BASO#
P4. DIFF Sensitivity	GRAN-X, GRAN-Y, WBC/BA-X, WBC/BA-Y, GRAN-Y (W)

6.2 Read FD (Floppy Disk)

Floppy disk provided with the Sysmex control blood includes the control blood information and target and limit# (%) values for both the manual and closed modes. This information can be registered automatically by using the "Read FD" program.

The FD file data includes the followings:

- Lot No.
- Analysis Mode
- Expiration Date
- Level (Normal, Abnormal Low, Abnormal High)
- Target and Limit # assayed default values, in both Manual Analysis and Closed Analysis modes.

NOTE: Since $\overline{X}$ M Control is designed for the use with patient blood, you cannot perform the "FD Read" program on the $\overline{X}$ M file.

(1) Press [QC] to display QC second menu.

(2) Press [Target/Limit] keypad from the second menu. The first page of QC File Information List will be displayed.

(3) Use the [↑] and [↓] keys to select the file to be registered from the reference list.

(4) Press [Read FD] keypad. The password entry screen will appear.

(5) Input the password and press [ENTER]. The Read FD ready message will appear. To cancel the process and exit the program, press [Cancel].

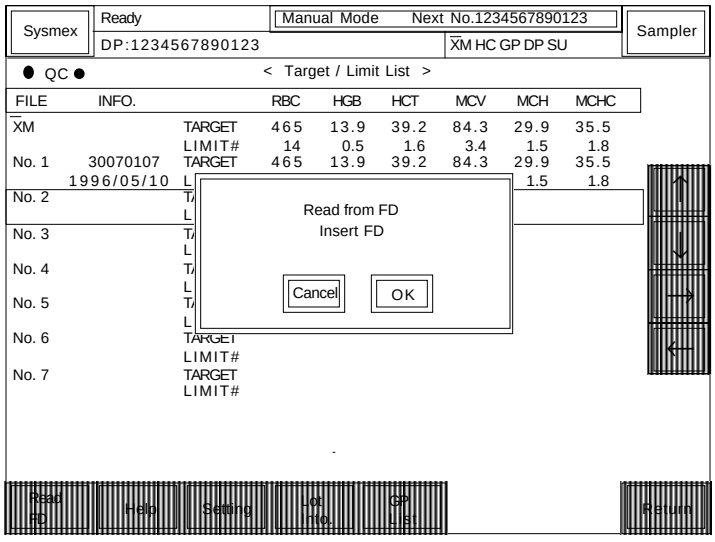


Figure 6-11: Read FD Ready Message Window

(6) Insert the floppy disk with the control blood data into the floppy disk drive, and press [OK].
A window will appear, containing a list of the files stored on the disk.

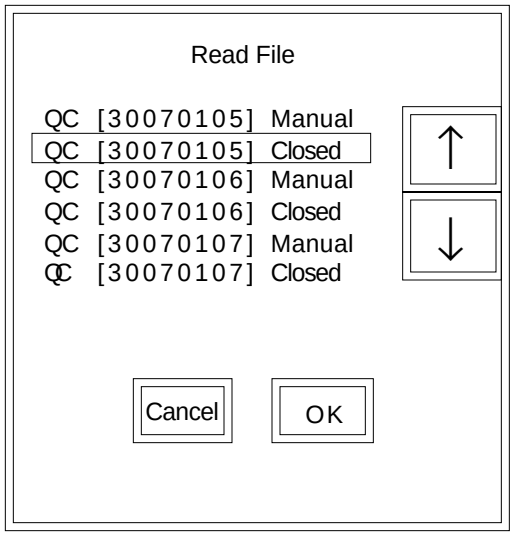
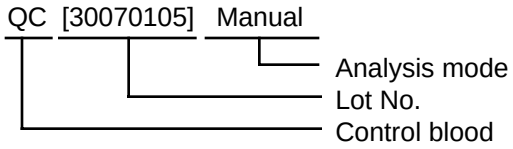


Figure 6-12: Read FD Window

The data file names indicate the following:

[Example]



(7) Use the [↑] and [↓] keys to move the cursor and select the required file. Press [Cancel] key to exit the "Read FD" program.

NOTE: Pressing the [↓] key when the cursor has reached the bottom of the list will move the cursor to the top of the list. Pressing the [↑] when the cursor has reached the top of the list will move the cursor to the bottom of the list.

(8) Press [OK]. The Download Item Setting window will appear as shown below.

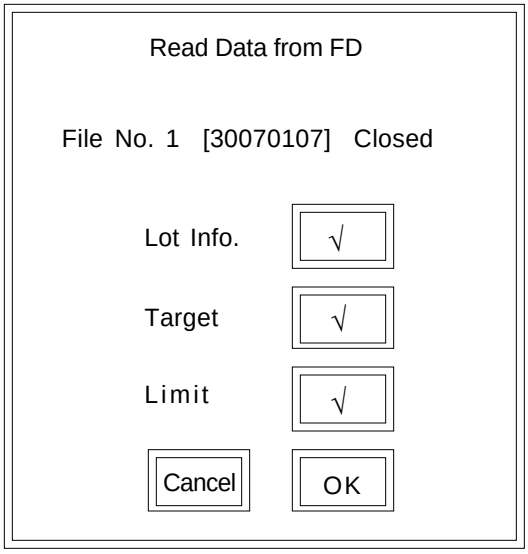


Figure 6-13: Download Item Setting Window

(9) Press the blank key to the right of item to set whether to down load it from the floppy disk file.
A check mark "√" will be placed in the pressed box.
To disable the down load setting, press the "[√]" mark on the right of the desired item.

Lot Info. : Select to register the level and expiration date of the control lot.
Target : Select to register the assayed Target values.
Limit : Select to register the assayed Limit values.

NOTE: To prevent a "Control Expired" error, make sure to register the expiration date for the control by selecting "Lot Info." in this program. The expiration date can be manually input using "Lot Info." program. Refer to *Section 6.6: Lot Information* in this chapter for the procedure.

(10) Press [OK]. The selected FD file assay value for the selected item is read into the file specified and the program exits. Pressing [Cancel] exits the program without reading the data from floppy disk.

This page is intentionally left blank.

6.3 Help

During the "Read FD" operation, the Help program can be accessed from the QC disk. Help consists of two pages, containing product insert information, limitations, instructions for use, and references.

(1) Press [QC] to display QC second menu.

(2) Press [Target/Limit] keypad from the second menu.
The first page of QC File Information List will be displayed with Target/Limit submenu.

(3) Press [Help] keypad. Insert FD message will be displayed.

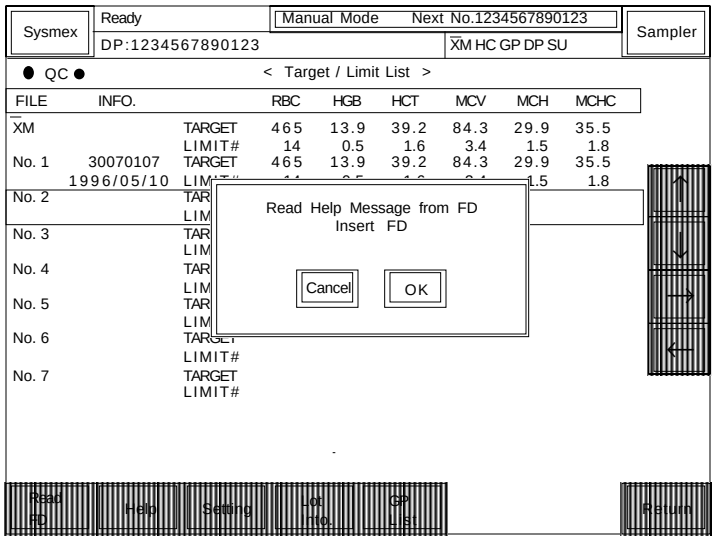


Figure 6-14: Help Insert FD Message Window

(4) Insert the QC disk into floppy disk drive, and press [OK] key.

(5) The Help message screen (Page 1) will appear.
Use the [↑] and [↓] keys to change the pages. To cancel the process and exit the program, press [Cancel] key.

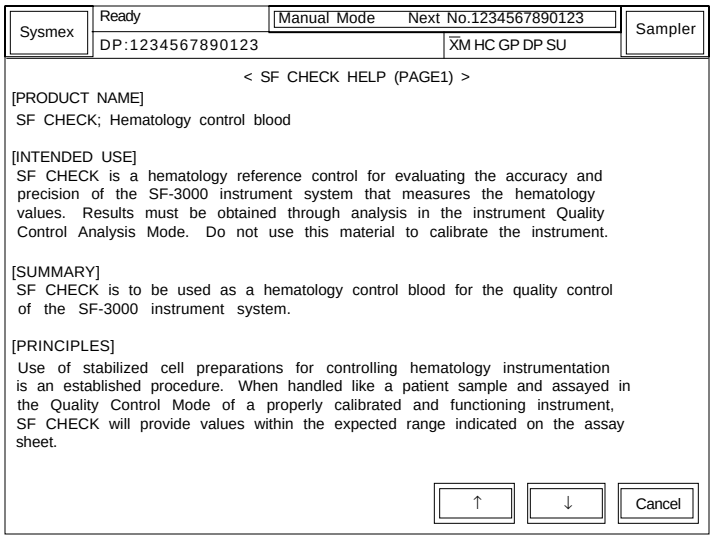

Sysmex
Ready
Manual Mode Next No.1234567890123
DP:1234567890123
XM HC GP DP SU
Sampler
< SF CHECK HELP (PAGE1) >
[PRODUCT NAME]
SF CHECK; Hematology control blood
[INTENDED USE]
SF CHECK is a hematology reference control for evaluating the accuracy and precision of the SF-3000 instrument system that measures the hematology values. Results must be obtained through analysis in the instrument Quality Control Analysis Mode. Do not use this material to calibrate the instrument.
[SUMMARY]
SF CHECK is to be used as a hematology control blood for the quality control of the SF-3000 instrument system.
[PRINCIPLES]
Use of stabilized cell preparations for controlling hematology instrumentation is an established procedure. When handled like a patient sample and assayed in the Quality Control Mode of a properly calibrated and functioning instrument, SF CHECK will provide values within the expected range indicated on the assay sheet.
↑
↓
Cancel

Figure 6-15: Help Message Screen (Page 1)

(6) Pressing the [Return] key returns the display to the screen displayed before the [Help] key was pressed.

NOTE: SF CHECK HELP messages are subject to change without notice.

6.4 Auto Setting

This program automatically sets the average of control data previously specified on the QC Chart as the target value.
This program also sets either 2SD or 3SD as the Limit# value, or sets either 2CV or 3CV as the Limit% value.

NOTE: The target/limit auto setting program uses the reference data (mean, SD, CV) computed using the QC chart in "Calculate" program. Obtain the reference data referring to *Section 7.3: Mean/SD* in this chapter before accessing the auto setting program.

(1) Press [QC] to display QC second menu.

(2) Press [Target/Limit] keypad from the second menu.
The first page of the QC File Information List will be displayed.

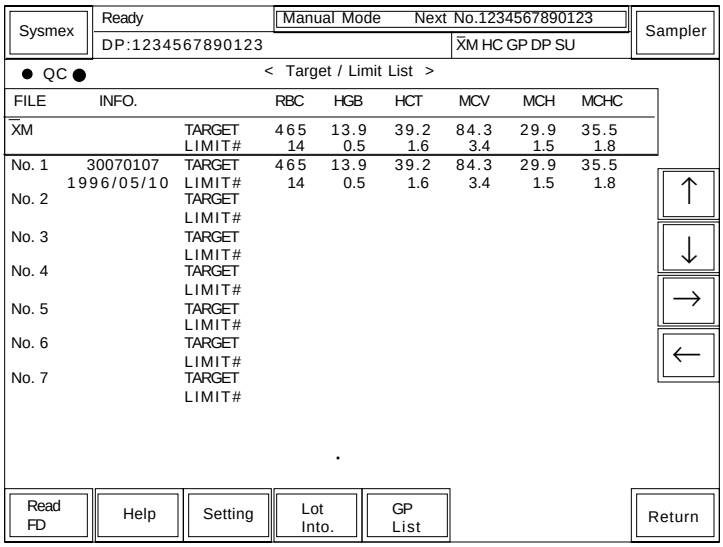


Figure 6-16: QC File Information List (P1: RBC)

(3) Use the [↑] and [↓] keys to move the cursor. Select the specific file in which target and limit values are to be registered.

(4) Press [Settings] keypad. The password entry screen will appear.

(5) Input the password and press [ENTER]. The Target/Limit Setting window will appear, together with reference values.

> **NOTE:** Obtain the reference data referring to *Section 7.3* in this chapter before accessing the auto setting program.

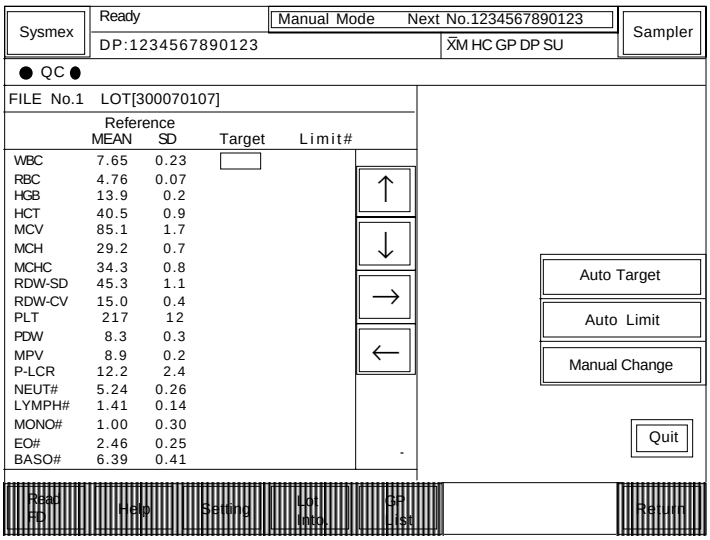


Figure 6-17: Target/Limit Setting Window

(6) Press [Auto Target] keypad.
The reference mean values displayed on the left will be copied and set as the target.

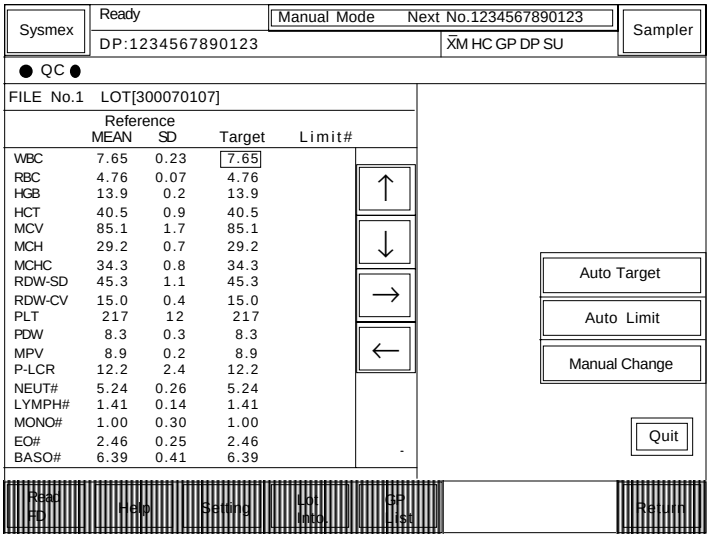


Figure 6-18: Auto Target Setting Screen

(7) Press [Auto Limit] keypad.
The Select Range window will appear. When the "System Settings" is set as Limit#, the selections will be 2SD and 3SD. When the Limit% is selected, 2CV and 3CV will be displayed. (Refer to *Section 3* in this chapter for the system settings.)

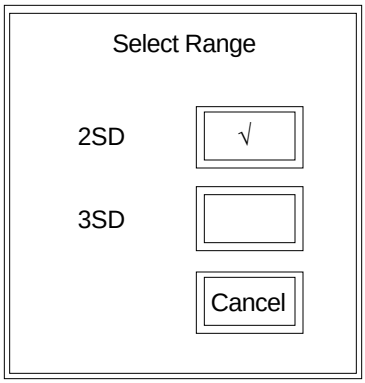


Figure 6-19: Select Range Window

(8) Press the box on the right of the desired range specification. A check mark "√" is placed. The window will disappear and the calculated Limit values using the reference SD or CV values will be displayed in the Limit column.
Pressing [Cancel] closes the window without changing the setting.

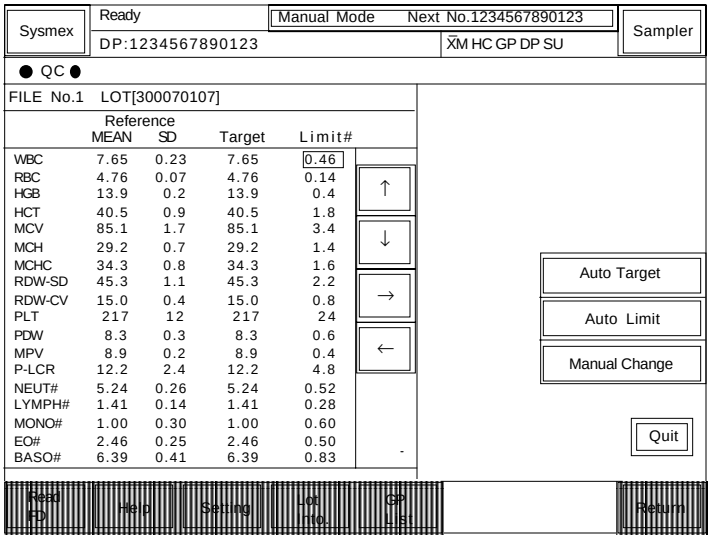


Figure 6-20: Auto Limit Setting Screen

(9) Press [Quit] key. The message "Set Target/Limit?" will appear.

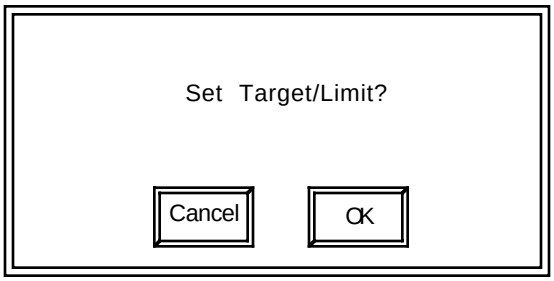


Figure 6-21: Confirmation Message Window

(10) Press [OK] key to set the new settings into the specified file and end the program. Press [Cancel] to cancel the new settings and end the program.

6.5 Manual Change

Normally, blood control target and limit# (%) values can be read from floppy disk using Read FD program. However, if the floppy disk is faulty, the target and limit# (%) values should be input manually by using this program.

NOTE: If control blood material other than SF CHECK is used , target and limit# (%) assay values for these parameters should be set to zero manually or these parameters should be excluded ("Not Used") using QC Parameter selection program so that they will not be monitored. Refer to *Section 4* in this chapter for exclusion.

GRAN-X GRAN-Y WBC/BA-X WBC/BA-Y GRAN-Y (W)

(1) Press [QC] to display QC second menu.

(2) Press [Target/Limit] keypad from the second menu.
The first page of the QC File Information List will be displayed.

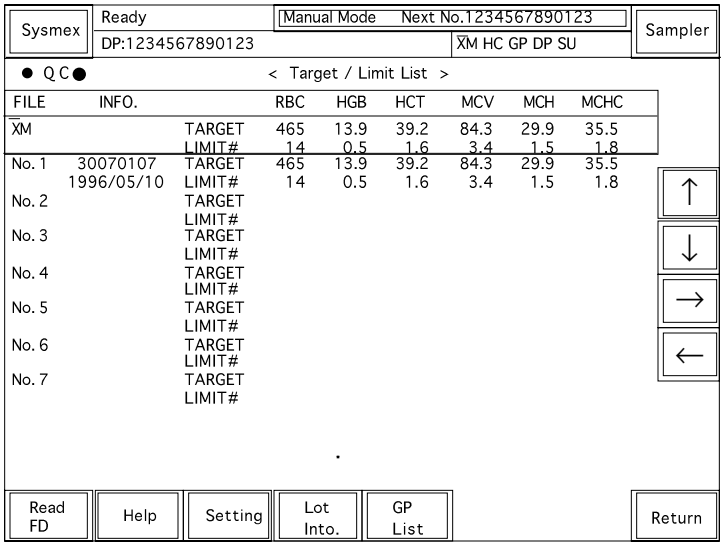


Figure 6-22: QC File Information List (P1: RBC)

(3) Use the [↑] and [↓] keys to move the cursor. Select the specific file in which target and limit values are to be registered.

(4) Press [Settings] keypad. The password entry window will appear.

(5) Input the password and press [ENTER]. The Target/Limit Setting window will appear, with the current target and limit# (%) values of the specified file No. displayed. The cursor will be on the WBC target value.

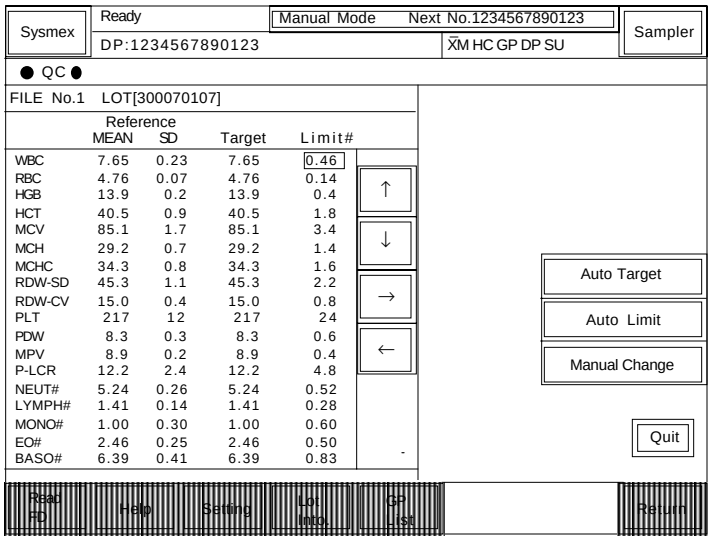


Figure 6-23: Target/Limit Setting Window

(6) Press [Manual Change] keypad. The Manual Setting Window containing the numerical keypads will appear.

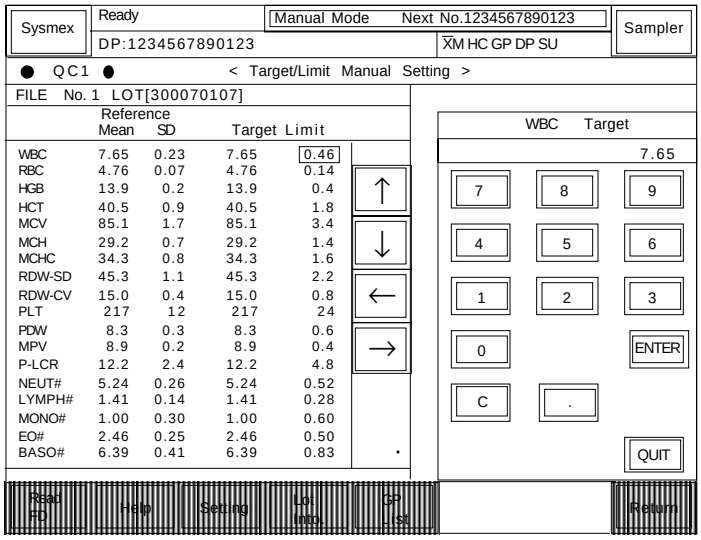


Figure 6-24: Manual Setting Window

(7) The item displayed above the numerical keypads can be manually input. Use the [←], [→], [↑] and [↓] keys to move the cursor to the values to be input. The cursor switches between the Target and Limit columns and moves up and down inside the columns.

NOTE:
- If the [↓] key is pressed when the cursor is at the bottom of the screen, the list will scroll up one item. (The cursor will be at the bottom of the screen.) However, if the cursor is on GRAN-Y(W), the list will not scroll when this key is pressed.
  If the [→] or [ENTER] key is pressed when the cursor is on the last Limit item on the screen, the list will scroll up one item and the cursor will move over to the Target side. (However, the list will not scroll and the cursor will not move if the cursor is on GRAN-Y(W) Limit when either of these keys are pressed.)
- If the [↑] key is pressed when the cursor is at the top of the screen, the list will scroll down one item. (The cursor will be at the top of the screen.) However, if the cursor is on WBC, the list will not scroll when this key is pressed.
  If the [←] key is pressed when the cursor is on the first Target item on the screen, the list will scroll down one item and the cursor will move over to the Limit side. (However, the list will not scroll and the cursor will not move if the cursor is on WBC Target when either of these keys are pressed.)

(8) Input the new values. The value where the cursor is positioned will be entered. When an incorrect value is input, press [C] to clear the value and input a correct value again.

(9) Press [ENTER] to confirm the new value. The cursor will move to the next value.

(10) Press [QUIT] key. The Target/Limit Setting Window will appear.

(11) Press [Quit] key. The confirmation window will appear as shown below.

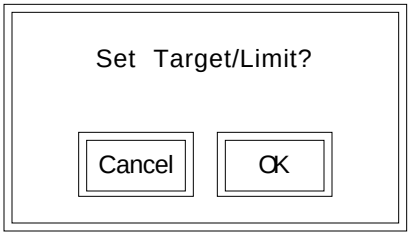


Figure 6-25: Confirmation Message Window

(12) Press [OK] key to set the new settings into the specified file and end the program. Press [Cancel] to cancel the new settings and end the program.

6.6 Lot Information

"Lot Information" refers to control blood material Lot No., Expiration Date, Level and Analysis Mode. This program enables the operator to set this information manually.

NOTE: Since $\overline{X}$ M file is designed for use with patient blood, you cannot enter the Lot Information on this file.

(1) Press [QC] to display QC second menu.

(2) Press [Target/Limit] keypad from the second menu.
The first page of the QC File Information List will be displayed.

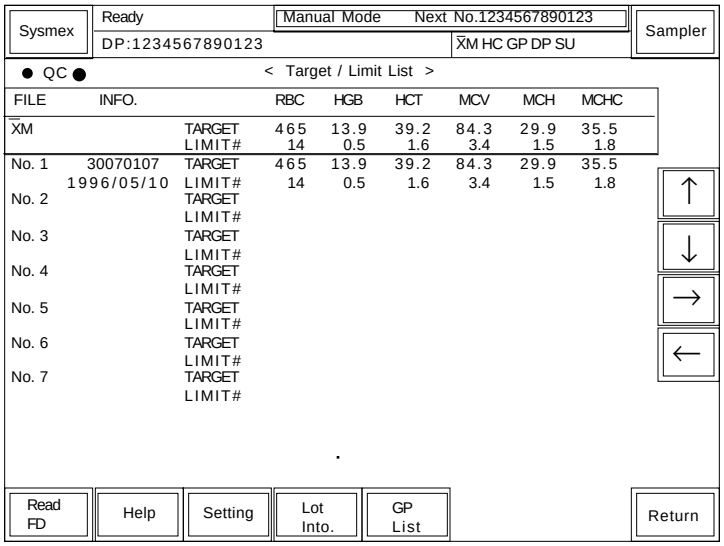


Figure 6-26: QC File Information List (P1: RBC)

(3) Use the [↑] and [↓] keys to move the cursor. Select the specific file in which control data information is to be registered.

(4) Press [Lot Info.] keypad from the submenu. The password entry window will appear.

(5) Input the password and press [ENTER]. The Lot Information screen containing lot information for the specified File No. will be displayed. The numeric keypads will also appear.

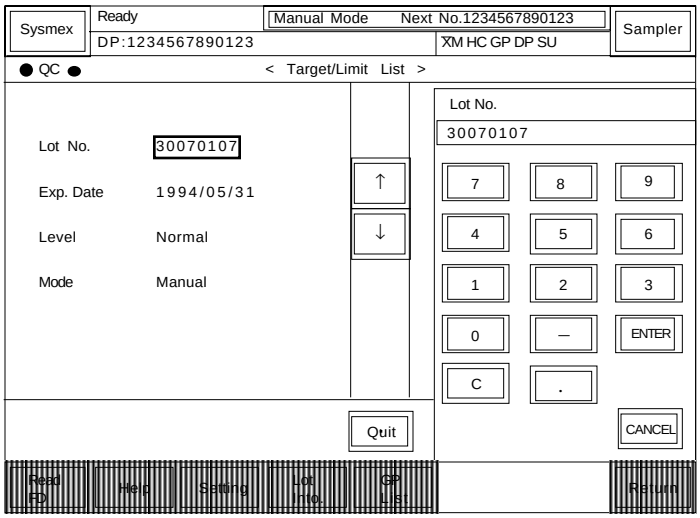


Figure 6-27: Lot Information Screen

(6) Use the [↑] and [↓] keys to move the cursor to the item to be changed.

(7) Input the new information as follows:

Lot No. : Use the numerical keys to input lot number and press [ENTER].
Exp. Date : Use the numerical keys to input the expiration date and press [ENTER].
Level : Pressing [Change] key alters the level sequentially from "Normal", "High" to "Low".
Mode : Pressing [Change] key alters the analysis mode "Manual" and "Closed".

NOTE: When the cursor moves to "Level" or "Mode", the numeric keypads disappears and the [Change] keypad appears instead.

(8) Press [Quit]. A lot information confirmation message will appear.

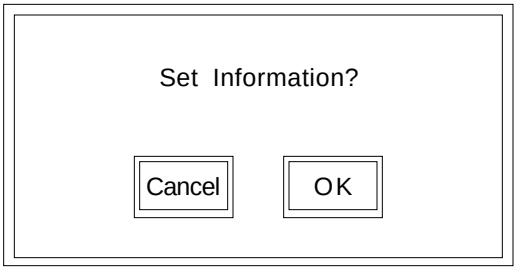


Figure 6-28: Lot Information Confirmation Window

(9) Press [OK] to write the input values into the specified file, and end the program. Press [Cancel] to cancel the new settings and end the program.

7. QC CHART

When the QC program is executed by pressing the [QC] keypad in the root menu, a QC Chart will be displayed as the QC main screen. Using this QC Chart, QC data output, Statistical calculations and control data point deletion can be performed.

(1) Press [QC] to display the QC second menu. The first page of the QC Chart (P1. RBC) will be displayed.
The QC chart title displayed is < $\overline{X}$ Chart > when $\overline{X}$ Control is the selected QC

NOTE: When the $\overline{X}$ Control is selected in the System Settings program, the QC chart title is < $\overline{X}$ Chart > even if L-J Control is performed, or vice-versa. Select the correct control method. Refer to *Section 3: System Settings* in this chapter.

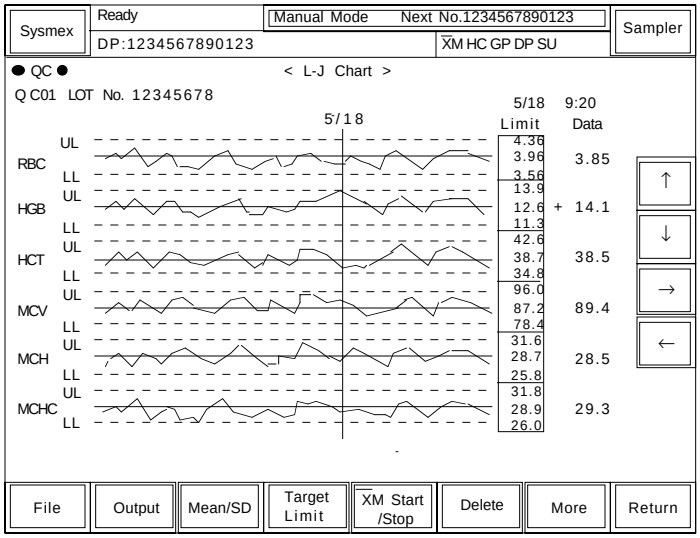


Figure 6-29: QC Chart Screen - P1. RBC

(2) Use the [↑] and [↓] keys to switch pages. The pages are switched in the following order:

QC Chart Display Items	
P1. RBC	RBC, HGB, HCT, MCV, MCH, MCHC
P2. PLT+5Calc.	RDW-SD, RDW-CV, PLT, PDW, MPV, P-LCR
P3. WBC+5DIFF#	WBC, NEUT#, LYMPH#, MONO#, EO#, BASO#
P4. 5DIFF%	NEUT%, LYMPH%, MONO%, EO%, BASO%
P5. DIFF Sensitivity	GRAN-X, GRAN-Y, WBC/BA-X, WBC/BA-Y, GRAN-Y (W)

(3) Use the [←] and [→] keys to move the vertical-line cursor left and right. The Data column on the far right of the screen displays the value of the data on which the cursor is positioned. If this value is outside the control limits, a "+" or "–" sign will appear to the left of it.

NOTE: The SF CHECK expresses Diff parameters as #, not as %. However, % as calculated by the microprocessor is displayed for your reference.

NOTE: After calibration has been performed, a yellow vertical dotted line, marking only the latest calibration appears on the QC Chart. Refer to *Section 7.5: Calibration History* in this chapter for more information.

NOTE:
- Control parameters where the limit# (%) has been set to zero do not appear on the QC Charts.
- Control data results containing "****" or "----" are not plotted, and extending lines from both sides of the point are not displayed on the chart.

Parameters on the QC Charts in which a control limit error has occurred are backlit in red. Control limit error is defined below. (Refer to the descriptions about QC error messages in *Section 8* or *Section 9* in this chapter.)

Control Limit Error Definitions

$\overline{X}$ /L-J Control : Current data exceeds the preset control limits, and a data within the previous 20 data points exceeds the preset limits in the same direction (i.e. higher or lower the limits). However, if calibration has been performed, apply this criterion only to data since the last calibration.

$\overline{X}$ M Control : If data exceeds the preset control limit in the same direction twice consecutively. However, if calibration has been performed, apply this criterion only to data since the last calibration.

7.1 Select File

The file No. must be specified using this program before "Output", "Mean/SD" and "Delete" programs are executed for the control data in the QC Chart.
Select either the $\overline{X}$ M file or one of the 12 $\overline{X}$ /L-J files.

(1) Press [QC] to display QC second menu.

(2) Press [File] keypad from the second menu. The File Selection window, containing a list of QC files with control material information for each file, will be displayed. The cursor is positioned on the file currently selected.

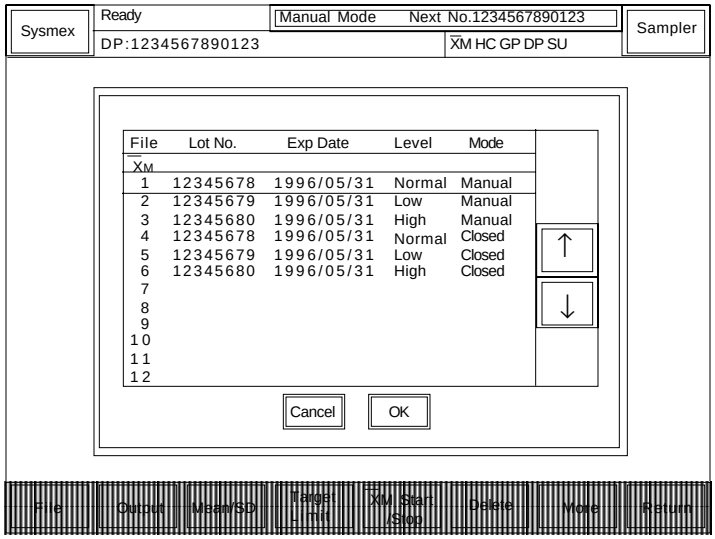


Figure 6-30: File Selection Window

(3) Use the [↑] and [↓] keys to move the cursor, and press [OK]. The QC Chart for the specified file No. will appear.
Pressing [Cancel] key will cancel the file selection and end the program.

7.2 Output QC Chart/Data

In this program, the QC Chart range specified is printed by a Graphic Printer. Also, use this program to output the QC data of the specified range on a QC Chart to a Graphic Printer, a Line Printer and/or a Host Computer.

(1) Press [QC] to display QC second menu.

(2) Press [Output] keypad from the second menu.
Two vertical-line cursors (A and B) appear on the screen. The cursors are moved to specify an output data range. Initially, the selected cursor is cursor B, and is backlit in green. To switch selected cursors, press the [Cursor] key in the menu line.
The data on which the selected cursor is positioned are displayed in the Data column.

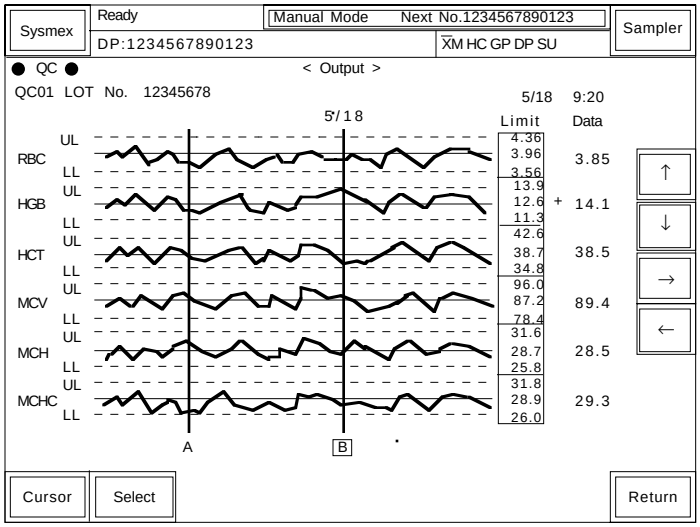


Figure 6-31: Output Range Setting Screen

(3) Use the [↑] and [↓] keys to switch screens.

Using the [←] and [→] keys, move the cursor to specify the range of data to be output.

NOTE:	The data on which the cursors are positioned is included in the range specified.

(4) Press the [Select] key. The Device Selection window will be displayed.

[GP Chart] : Press to print the QC Chart of specified range to a Graphic Printer.
[GP List] : Press to print the QC data of specified range to a Graphic Printer.
[HC] : Press to output the QC data of specified range to the Host Computer.

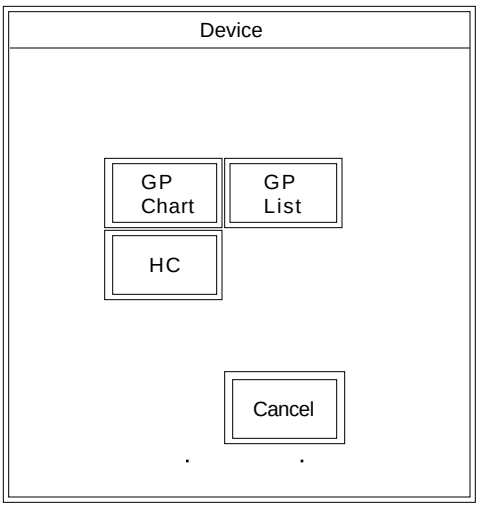


Figure 6-32: Output Device Selection Window

7.3 Mean/SD (Calculation)

This program automatically computes the mean, standard deviation (SD) and coefficient of variation (CV) for the data specified using the two vertical-line cursors on the QC chart, and displays them at the far right of the screen.

(1) Press [QC] to display the QC second menu.

(2) Press [Mean/SD] keypad from the second menu.
Two vertical-line cursors (A and B) appear on the screen. The cursors are moved to specify the data range for Mean/SD computation. Initially, the selected cursor is cursor B, and is backlit in green. To switch selected cursors, press the [Cursor] key in the menu line.

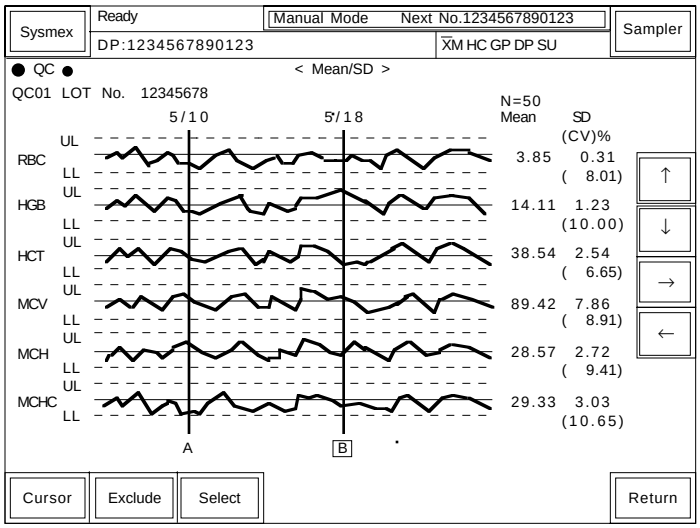


Figure 6-33: Computation Range Selection Screen

(3) Use the [↑] and [↓] keys to switch screens.

(4) Check the control data.
If there is unsuitable data for target and limit value computations, sandwich the data between the 2 cursors by using the [←] and [→] keys. Then, press [Exclude] keypad. The exclusion confirmation message will appear.

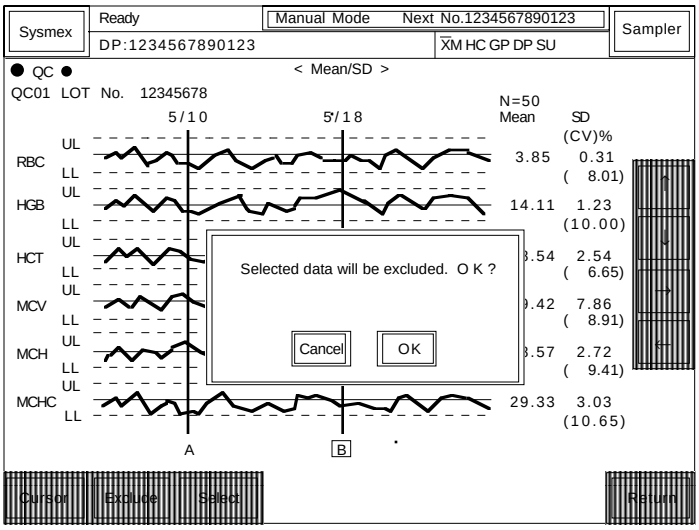


Figure 6-34: Exclusion Confirmation Message Window

(5) Press [OK] to delete the data positioned under and between the 2 cursors from the QC Chart.
Press [Cancel] key to cancel the program without excluding the data.

NOTE: The data on which the cursors are positioned are also excluded.

(6) Using the [←] and [→] keys, move the cursor to specify the range of data for computation. Mean, SD and CV values calculated from the data (max.180) between the cursors are displayed at the right of the screen.

(7) Press the [Select] key. Confirmation Window will appear as shown below. Press [OK] to set the current Mean, SD and CV values as reference data for the target/limit auto setting programs. Refer to *Section 6.4: Auto Setting* in this chapter.

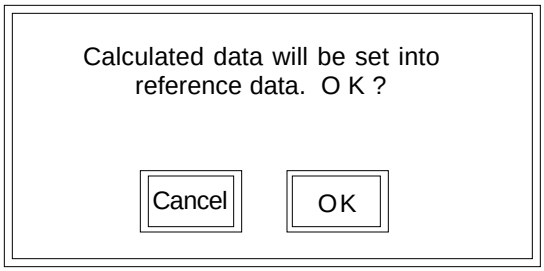


Figure 6-35: Set Reference Confirmation Window

7.4 Delete Plot

Use this program to delete the data from the QC Chart specified by using the 2 vertical-line cursors.

(1) Press [QC] keypad in the root menu. The QC second menu will be displayed.

(2) From the QC submenu, select [Delete]. The password entry window will appear.

(3) Input the password and press [ENTER].

(4) From the Delete submenu, press [Plot].
Two vertical-line cursors (A and B) appear on the screen. These cursors are moved to specify a deletion data range. Initially, the selected cursor is cursor B, and is backlit in green. To switch selected cursors, press the [Cursor] key.

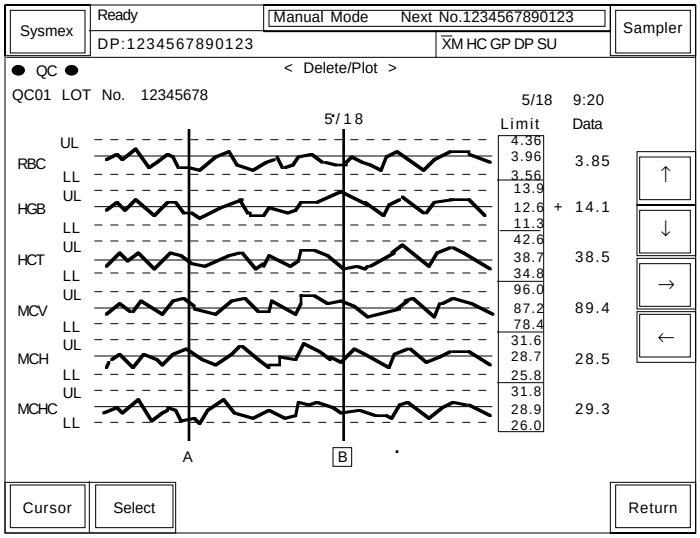


Figure 6-36: Deletion Range Setting Screen

(5) Use the [↑] and [↓] keys to switch screens.
Using the [←] and [→] keys, move the cursor to specify the range of data to be deleted.

NOTE:	The data on which the cursors are positioned are also deleted.

(6) Press [Select] key. The deletion confirmation window will appear.

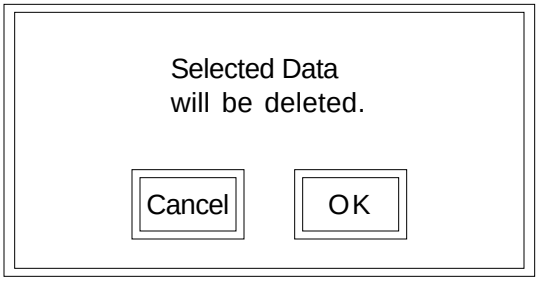


Figure 6-37: Delete Confirmation Message

(7) Press [OK] to delete the data under and between the 2 cursors.
Press [Cancel] to cancel the deletion.

NOTE:	The data cannot be recovered once deleted.

7.5 Cal. History

After calibration has been performed, a yellow vertical dotted line, marking only the latest calibration appears on the QC Chart. This line is midway between two plotted points. The calibration history can be referred in QC mode for operator's convenience to confirm the calibrated parameters.

(1) Press [QC] keypad in the root menu. The QC second menu will be displayed.

(2) From the QC submenu, select [Cal. History].

> **NOTE:** If [Cal. History] keypad is not displayed on the LCD, press [More] to change the displayed root menu.

(3) The calibration history will appear. Refer to *Chapter 7: Calibration* for detail of the calibration history.

8. MANUAL QC ANALYSIS

$\overline{X}$ Control and L-J Control can be performed in the Manual mode, Closed mode, or Manual CP mode using control blood material. The overview of the QC analysis in these three modes is described in this section. Refer to *Chapter 2, Section 3: QUALITY CONTROL ANALYSIS* for step-by-step procedures to run QC in each mode.

(1) Make sure that the instrument is in the Ready status.

(2) Select the analysis mode, Manual or Closed.

(3) Specify the file No. in which the QC data are to be stored.

(4) Verify that the control lot information is correctly set for the selected QC file, if necessary.

(5) Analyze the control material in manual (open or closed) mode. Refer to *Chapter 2, Section 4* for the procedures.

(6) After the analysis is completed, the results are displayed and stored in the memory.

NOTE: The analysis results up to 1000 QC samples are stored in the memory.

- When L-J Control program is used:
  The QC analysis results are displayed as shown in Figure 6-38a. The sample No. on the graphic display is indicated as "QC01" (see Figure 6-38c).

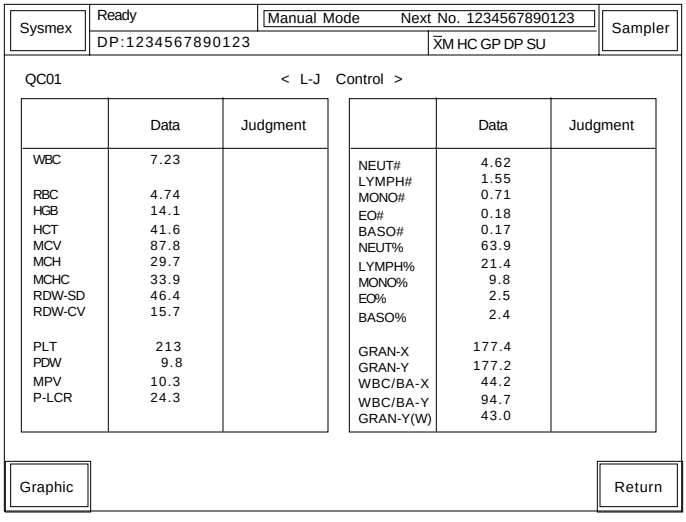


Figure 6-38a: QC Data Display Screen (L-J Control)

- When $\overline{X}$ program is used:

  The results of the first analysis is displayed in the "X1" column when completed. The sample No. on the graphic screen is shown, for example, as "QC01-1". When the second analysis is completed, the results are displayed in "X2" column. Then, the mean (average) values of the first and the second analysis results will be displayed in the "Mean" column. Refer to Figure 6-38b. The sample No. on the graphic screen is indicated as "QC01" (see Figure 6-38c).

NOTE: Two analysis results obtained consecutively without any abnormality are used for the $\overline{X}$ Control.

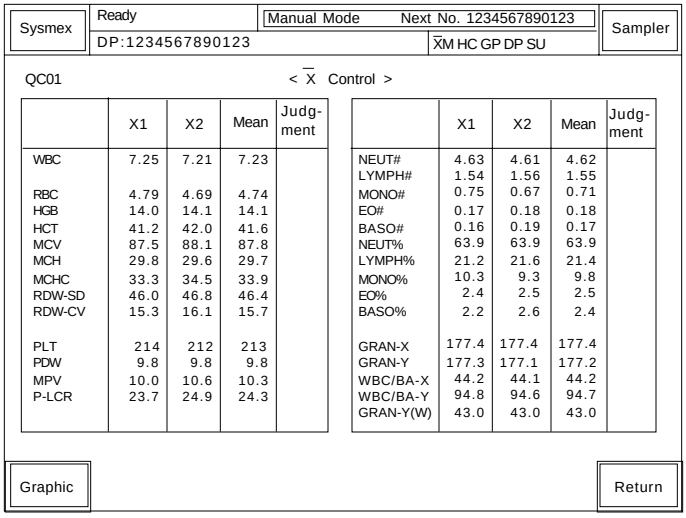


Figure 6-38b: QC Data Display Screen ($\overline{X}$ Control)

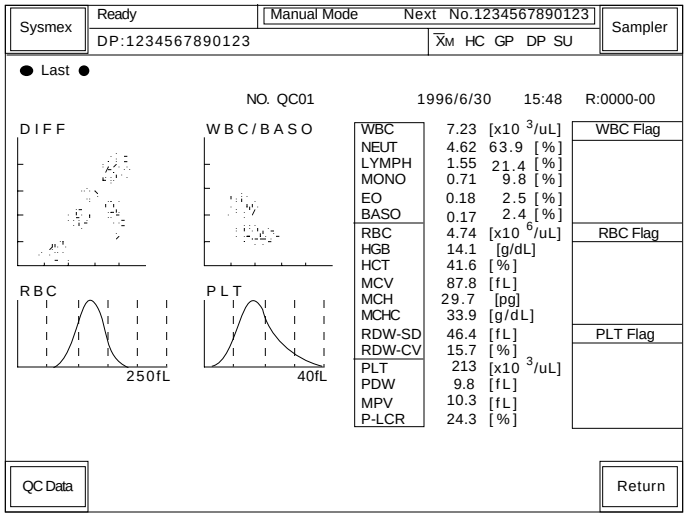


Figure 6-38c: Control Data Graphic Display

Error Messages relating to QC analysis:

• < $\overline{X}$ Limit Error> or <L-J Limit Error>

This message appears in the system status area (upper portion of the LCD), when the analyzed data has exceeded the control limit.

The "+" or "-" sign in yellow backlight will be displayed in the "Judgment" column and the "Check Control Chart" message window appears. On the graphic display, the "+" or "-" sign in yellow backlight will also be added to the parameter which is outside the control limits. Check the control chart and review the control data. Reanalyze the sample, if needed. Refer to *Chapter 6: Quality Control*.

When the message "Reanalyze Control" appears, the analyzed data is more than 3 times the limit and will not be recorded in memory. The "+" or "-" sign in red backlight will be displayed in the "Judgment" column. On the graphic display, the "+" or "-" sign in red backlight will also be added to the parameter which is outside the control limits. Reanalyze the sample.

• <QC Analysis Error>

This message appears if an analysis error occurs during QC analysis. Reanalyze the sample.
The results are not plotted, or not stored as control data.

• Control Expired

This message appears if the analyzed control lot is expired. Analyze a new lot.
The results are not plotted, or not stored as control data.

NOTE:	The expiration date of SF CHECK is monitored if the expiration date information is entered in the control file. "Control Expired" will be reported when SF CHECK is analyzed and the lot has already expired. This error also occurs when the expiration date is not entered in the control file.

NOTE:	Refer to *Chapter 8: Troubleshooting* for QC error information.

9. SAMPLER QC ANALYSIS (L-J)

L-J Control can be performed in the Auto mode using control blood material. The overview of the QC analysis in Auto mode is described in this section. Refer to *Chapter 2, Section 3: QUALITY CONTROL ANALYSIS* for step-by-step procedures to run QC in Auto mode.

NOTE:
- $\overline{X}$ Control cannot be performed using auto mode.
- L-J Control can be performed using auto mode even if the system setting is $\overline{X}$ Control.

(1) Check the volume of control material.

(2) Verify the control lot information for the control file to be used.

NOTE: When SF CHECK is used, files 1 through 12 can be designated in advance.

(3) Place the vials of SF CHECK in a sample rack, and set on the Sampler Unit.

NOTE: The control material can be placed in a rack and analyzed together with routine patient samples. The control samples can be identified by the ID reader or by the registered information in the work list, and the data are automatically plotted as control data.

(4) Analyze the control material in the auto mode. Refer to *Chapter 2, Section 4.3: Auto Mode*.

(5) After analysis is completed, the analysis results are displayed as shown in Figure 6-39. The sample No. is indicated as "QC02". Every data is plotted as the L-J control data when each analysis is completed.

NOTE: The QC Data Display screen as shown in Figure 6-38a on page 6-41 will not be displayed for the QC analysis in Auto mode.

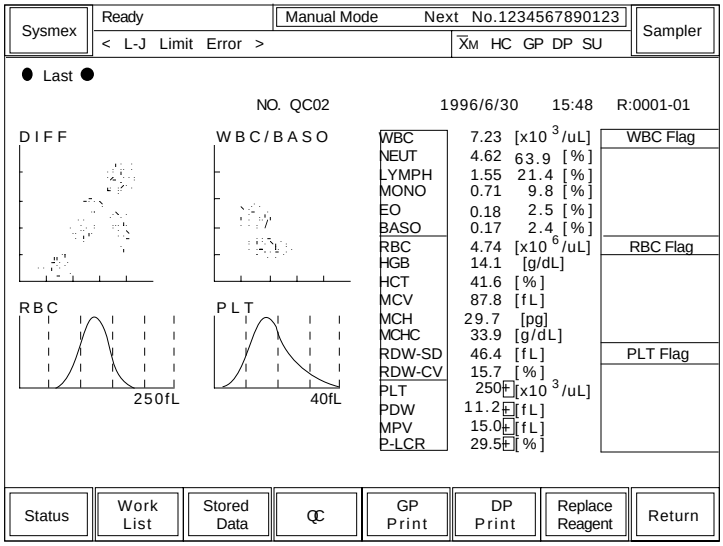


Figure 6-39: Control Data Display (Auto Mode)

If the ID reader is installed, the lot number is read from the bar code label and the data of the control sample is automatically stored in the specified QC files.
If the control lot number is registered for a QC file and the lot number is entered in the Work List, the control vial is identified during the auto mode analysis and the results will automatically be stored in the QC file. Refer to *Chapter 3* to register the control information in Work List.

Error Messages relating to QC analysis:

- < $\overline{X}$ Limit Error> or <L-J Limit Error>

This message appears in the system status area (upper portion of the LCD), when the analyzed data has exceeded the control limit.

When the Limit Error is accompanied by the "Check Control Chart" message, check the control chart and review the control data. Reanalyze the sample, if needed.
The "+" or "-" sign in yellow back-light will be added to the parameter which is outside the control limits.
The results are plotted on the QC chart as control data points, and are stored in the QC file.

When it is accompanied with "Reanalyze Control" message, the analyzed data is more than 3 times the limit. Reanalyze the sample.
The "+" or "-" sign in red back-light will be added to the parameter which is outside the control limits.
The results are not plotted, or not stored as control data.

• <QC Analysis Error>
This message appears if an analysis error occurs during QC analysis. Reanalyze the sample.
The results are not plotted, or not stored as control data.

• Control Expired
This message appears if the analyzed control lot is expired. Analyze a new lot.
The results are not plotted, or not stored as control data.

NOTE: The expiration date of SF CHECK is monitored if the expiration date information is entered in the control file. "Control Expired" will be reported when SF CHECK is analyzed and the lot has already expired.
This error also occurs when the expiration date is not entered in the control file.

NOTE: Refer to *Chapter 8: Troubleshooting* for QC error information.

10. QC METHODS AND APPLICATIONS

Quality Control in the SF-3000 features the commercial control applications $\overline{X}$ Control or L-J Control, and also $\overline{X}$ M Control, which uses routine patient samples.

10.1 $\overline{X}$ Control

$\overline{X}$ Control corresponds to the $\overline{X}$ -R Control used in earlier models. The "R" (=difference) has been dropped because the reproducibility of the instrument has improved and the use of R is decreasing. Another reason is that daily monitoring is now increasingly favored as a cost-saving method. Because the control blood is synthetic, changes in the reagent may not produce the same changes in the control blood as in human blood. The control blood can be used for a long period of time before it reaches its expiration date, and values are displayed as reference values.

$\overline{X}$ Control uses control blood to perform daily monitoring of the instrument. It analyzes the control blood twice in succession, and takes the average of the two analyses as the control data point. Because the control data is an average value, it is hardly affected by the reproducibility.

10.2 L-J Control

Like $\overline{X}$ Control, L-J also uses control blood to perform daily monitoring of the instrument. It uses the results of a single analysis of the control blood as the control data point.
The range of control blood controlled by L-J Control is broader than the range controlled by $\overline{X}$ Control. Consequently, L-J Control is more liable to be affected by reproducibility.

If the instrument has a sampler, L-J control can be executed using the Auto mode analysis. QC bar codes are attached to the QC blood tubes, and when Auto mode analysis is performed, the results of the control blood are stored in the L-J file whose number is identified by the bar code. By using the auto mode analysis, L-J Control can perform hourly monitoring in addition to daily monitoring.

In the QC program, either $\overline{X}$ or L-J Control can be selected in the "System Settings" program.

10.3 $\overline{X}$ M Control

The SF-3000 has $\overline{X}$ M Control for monitoring instrument stability over time. $\overline{X}$ M Control calculates the weighted averages of batches of samples in normal routine analysis, and compares the control values obtained for the different samples. It cannot control a batch until it has been processed, but is effective in checking hour-by-hour changes and can detect changes in the instrument and in the reagents with great sensitivity. However, $\overline{X}$ M Control is affected by variations in the analysis values within a batch, and if a limit error occurs, the sample analysis values should be checked.

The control program uses the $\overline{X}$ B algorithm published by Dr. Brian S. Bull. This algorithm is formulated using the three blood cell indices (MCV, MCH and MCHC). $\overline{X}$ M Control is used in the SF-3000 because of the large number of control parameters (28).

NOTE: The "M" of "$\overline{X}$ M" stands for "moving". (Or, more precisely, "weighted moving average".)

This program's computations are performed using the following equations:

$$\overline{X}_M(i) = \overline{X}_M(i-1) + SGN\left\{\sum_{j=1}^{N} SGN\left[X(j,i) - \overline{X}_M(i-1)\right] \sqrt{\left|X(j,i) - \overline{X}_M(i-1)\right|}\right\} \cdot F$$

$$F = \left\{ \frac{\sum_{j=1}^{N} SGN\left|X(j,i) - \overline{X}_M(i-1)\right| \sqrt{\left|X(j,i) - \overline{X}_M(i-1)\right|}}{N} \right\}^2$$

Figure 6-40: Equation (1)

Here, $\overline{X}$ M (i) is the $\overline{X}$ M value for the i-th batch, $\overline{X}$ M (i-1) is the $\overline{X}$ M value for the (i-1)th batch, $\overline{X}$ (j, i) is the j-th analyzed value in the i-th batch, and N is the number of samples in a batch.

The $\overline{X}$ M quality control program is based on the fact that once the characteristics of a population have been established for a particular institute, the parameters will remain stable within these limits. The characteristics of the population can be represented by the $\overline{X}$ M limits, which are computed using at least 30 $\overline{X}$ M control data. Equation 1 contains the techniques of trimming and smoothing.

- **Trimming**

Trimming consists of reducing the effect on the overall average of analysis data that diverges greatly from the estimated average. The greater the divergence of the data, the larger the trimming is made. Here is an example of trimming performed on a batch of 5 samples.

Previous MCV batch average $\overline{X}$ M (i-1) = 90.

Previous MCV batch average $\overline{X}_M$ (i - 1) = 90.

Current Batch		Xj	Xj-$\overline{X}_M$ (i-1)	SGN (Xj-$\overline{X}_M$ (i-1))	$\sqrt{\lvert Xj-\overline{X}_M (i-1) \rvert}$
Sample	1	92	2	1.41	
Sample	2	84	- 6	- 2.45	
Sample	3	54	- 36	- 6.00	
Sample	4	95	5	2.24	
Sample	5	88	- 2	- 1.41	
	N = 5		Σ = - 37	Σ = - 6.21	
			$\frac{\Sigma}{N}$ = - 7.40	$\frac{\Sigma}{N}$ = - 1.24	

$X = 90 - 7.40 = 82.60$ $\quad \overline{X}_M (i) = 90 - (-1.24)^2 = 88.46$

Negative when $\frac{\Sigma}{N} < 0$

Positive when $\frac{\Sigma}{N} \geqq 0$

Figure 6-41: Equation (2)

Sample 3, which has an abnormal value, will greatly affect the arithmetic mean, but trimming rectifies this and minimizes the effect on $\overline{X}$ M (i).

- **Smoothing**

The smoothing technique uses data from the previous batch to reduce individual data point fluctuations in the current batch. Here is an example of smoothing performed on a batch of 5 samples:

Previous MCV batch average $\overline{X}_M$ (i - 1) = 9 0

Current Batch		Xj	Xj-$\overline{X}_M$ (i-1)	SGN (Xj-$\overline{X}_M$ (i-1))	$\sqrt{\lvert Xj-\overline{X}_M (i-1) \rvert}$
Sample	1	9 2	2	1. 4 1	
Sample	2	8 4	- 6	- 2. 4 5	
Sample	3	8 4	- 6	- 2. 4 5	
Sample	4	9 5	5	2. 2 4	
Sample	5	8 8	- 2	- 1. 4 1	
N = 5			$\sum$ = - 7	$\sum$ = - 2. 6 6	
			$\frac{\sum}{N}$ = - 1. 4 0	$\frac{\sum}{N}$ = - 0. 5 3	

X = 9 0 - 1. 4 0 = 8 8. 6 0

$\overline{X}_M (i) = 90 - (-0.53)^2 = 89.72$

Negative when $\frac{\sum}{N} < 0$

Positive when $\frac{\sum}{N} \geqq 0$

Figure 6-42: Equation (3)

The average provided by the $\overline{X}$ M Control method is closer to the previous batch average than would be the case if an arithmetic mean were used. Thus the smoothing procedure makes more practical use of the data.

* Limitations of $\overline{X}$ M Control

Normally, one control data point is plotted for each batch of 20 samples (unless otherwise specified). However, the following data are excluded from $\overline{X}$ M computation:

1. Data having sample ID No. "0" (zero)
2. Auto calibration data and data for $\overline{X}$ or L-J control
3. Data assumed to be a blank or auto rinse
4. Data which exceeds the instrument linearity range, or unreliable data
5. Data reported with analysis error
6. Data containing a parameter displayed as "****" or "----" because of abnormal cell size distribution
7. Data generated for a PDA test

NOTE: Parameters for QC having the limit#(%) of 0 (zero) do not appear on the QC Charts. However, data in item 6. above, having patient mark limit#(%) value set at 0 (zero) will be included in $\overline{X}$ M computation.

11. VARIABLE TARGET FUNCTION

The variable target function serves to calculate a control target value automatically from the data stored in the control file. The variable target function operates in both the $\overline{X}$ M and $\overline{X}$ /L-J control programs when the target value is set at zero. The variable target value calculated by this function does not appear in the QC setting programs. It appears only in the LIMIT column of the QC charts.

NOTE: When the $\overline{X}$ M Control data becomes 5 or less, the target values will be automatically set to zero (0) and the variable target function will operate in the $\overline{X}$ M Control program.

11.1 How Target Values Are Calculated

Here the target value calculation operation is explained in an example using an empty file (file with no control data).
In this example, the parameter selected is RBC, the target is set at 0 and the limit (%) is set at 2.3%. The limit above and below this target are calculated from the following equation. (The limit values thus obtained are rounded up. UL = upper limit, LL = lower limit.)

Range (UL and LL) = Target X Limit (%) / 100

(1) 4.5 million is input as the first RBC control data. The variable target will be set at 4.50, and the QC Chart will show the values in the figure on the right.

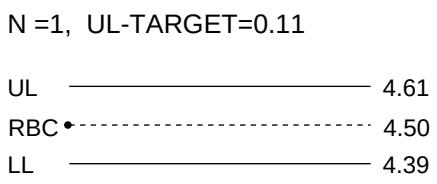


Figure 6-43: First Control Value

(2) 4.45 million is input as the second RBC control data. The variable target remains the same, because the denominator (N-1) in the equation X/N-1 is 1 in this instance.

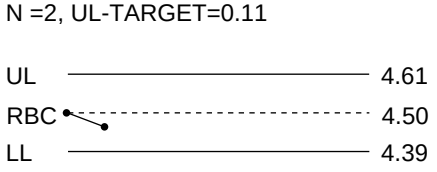


Figure 6-44: Second Control Value

(3) 4.52 million is input as the third RBC control data. The variable target changes to 4.48 (= (4.50+4.45)/2).

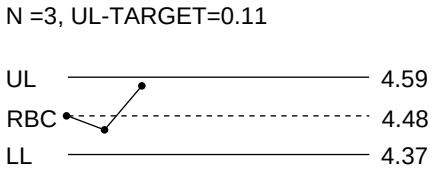


Figure 6-45: Third Control Value

(4) 4.21 million is input as the fourth RBC control data. The variable target, calculated using all three of the previous control data, changes to 4.49 (= (4.50+4.45+4.52)/3).

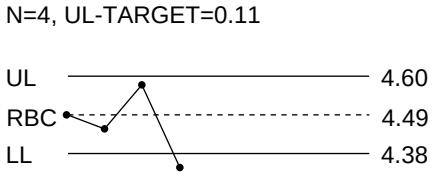


Figure 6-46: Fourth Control Value

The variable target function is useful for setting control target values when the instrument is monitored using control blood (the analyzed values for which, unlike calibrator, are not reliable in an absolute sense).

11.2 Variable Target Function and Erroneous Data

To ensure that the variable target function operates smoothly, control data that exceed the preset control limits by a factor of 3 are not entered in the QC Charts.

[Example]

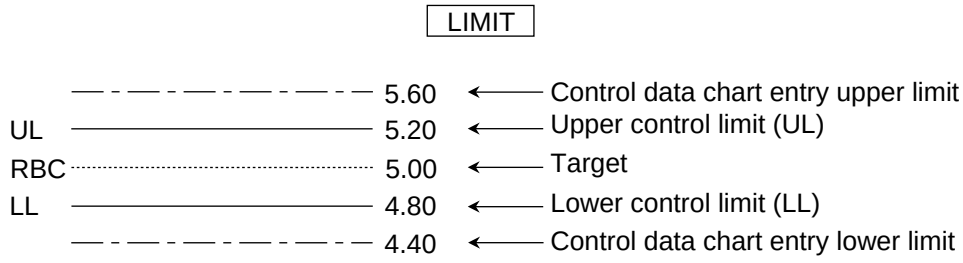


Figure 6-47: QC Control Chart Definition

Assume that the control limits are the values given above. If the control data is 5.21 million, the message "Check QC Chart" will be displayed, but the data will be entered on the chart. If the control data is 5.61 million however, it will not be entered on the QC Chart, and the message "Reanalyze sample" will be displayed.

12. CONTROL CHART DEFINITION

In the SF-3000, the Levy-Jennings Method is used as a basic principle for reading the QC Charts. This method consists of the following operation: If the latest control data point is outside the control limits, the last 20 (including the latest) data points are searched for a point that is outside the same limit as the latest data point. If such a point is found, the data is judged to be abnormal. If no such point is found, $\overline{X}$ /L-J control is repeated, and if the result of the repeat control is inside the control limits, the quality control is not judged abnormal. Naturally, if the repeat control result is outside the same limit as the previous result, the quality control is judged abnormal.

- How abnormality is displayed

If the quality control is judged abnormal, the relevant parameter name appears backlit.

Example displays: Abnormality judged

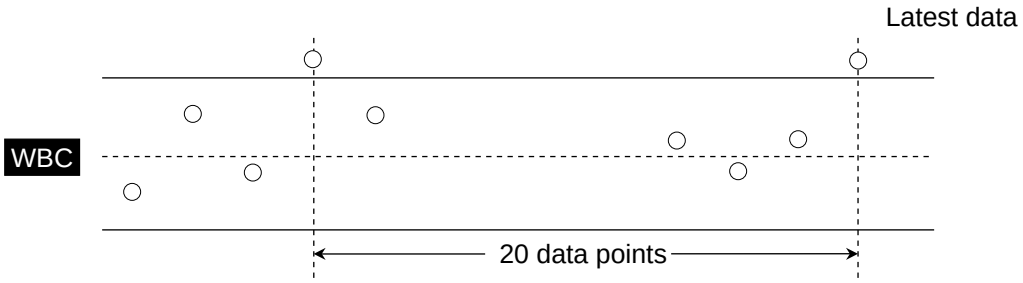


Figure 6-48: Quality Control Error Display

Example displays: No abnormality judged

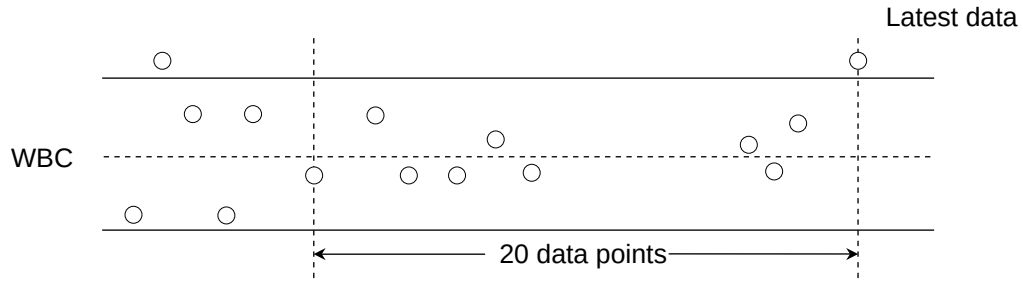


Figure 6-49: Quality Control No-Error Display

CHAPTER 7 CALIBRATION

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1. INTRODUCTION

Calibration is performed to compensate for any bias generated by the pneumatic system, hydraulic system, and electrical system which may influence the accuracy of results. It is thus vital for the maintenance of system accuracy. Compensation for bias is accomplished by entering a compensation factor into the instrument's computer.

Initial calibration is performed during installation by the Sysmex representative. Following the installation calibration, the operator is only requested to calibrate the instrument on an "as needed" basis, and maintain good QC practices, to ensure the accuracy of the system.

This chapter covers the process and procedures necessary to calibrate the instrument for HGB (hemoglobin) and HCT (hematocrit). Calibration of the SF-3000 can be performed either automatically or manually.

1.1 Calibration Implementation Standards

Calibration is not required at specified periodic intervals. Instead, it is recommended that the laboratory performs calibration or calibration verification when any of the following occurs:

- There is major preventative maintenance performed or critical parts are replaced, such as manometer, aperture or circuit boards.
- Controls begin to reflect an unusual trend or are outside of acceptable limits, and cannot be corrected by maintenance or troubleshooting the instrument.
- The laboratory's established schedule requires more frequent calibration or calibration verification.

1.2 Calibration Samples

Five to ten samples of fresh normal whole blood should be used for the calibration. The samples should be analyzed within six hours of collection. Observe the following recommendations when selecting blood for calibration purposes:

- The samples should be collected from persons who are not on medication.
- The samples should be morphologically and numerically normal by your laboratory criteria.
- Lipemic, icteric, and hemolyzed specimens must be avoided.
- The anticoagulant should be of proper type and in proportion with the sample.
- The volume of whole blood per sample should be greater than 2 mL (smaller volumes may indicate poor sample collection and increase the risk of hemolysis or have incorrect anticoagulant proportions).
- Commercial control blood should not be used as a calibrator. It is intended for quality control only.

NOTE: Do not use SF CHECK for calibration. SF CHECK was developed especially as control blood and not for use in calibration.

1.3 Reference Values

Accurately measure the HGB concentration and the HCT value for each of the 5-10 whole blood samples prepared for calibration. These results will be the reference values for the samples.

- HGB concentration : Cyanmethemoglobin Method
- HCT value : Microhematocrit Method

NOTE:
- HGB reference value will be influenced by WBC count, diluent, lyse reagent, HGB light source, temperature, etc.
- HCT reference value decrease significantly due to excessive anticoagulant.

2. HGB/HCT AUTO

Using five to ten samples of fresh normal whole blood, perform calibration of the SF-3000 including the following four steps:

1. Enter reference values.
2. Analyze samples.
3. Review and Select data for editing.
4. Update calibration values.

2.1 Overview of the HGB/HCT Auto Program

(1) Press [More] to change the displayed root menus, then [Calib.] keypad. The Calibration screen containing submenu will appear as shown in Figure 7-1.

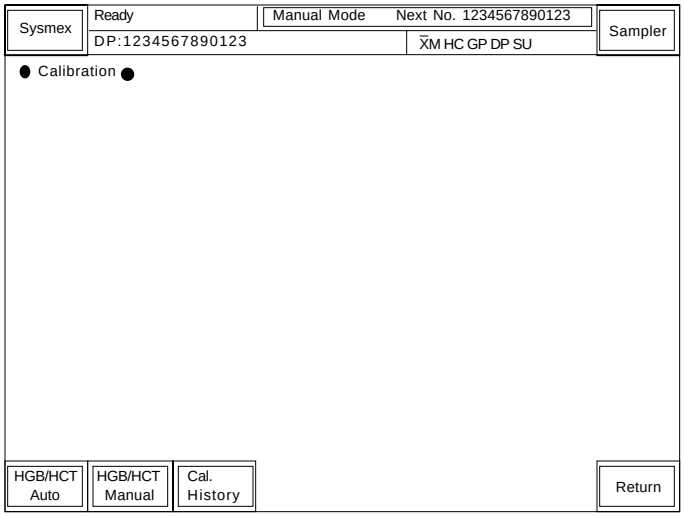

Figure 7-1: Calibration Screen

(2) Press [HGB/HCT Auto]. The message "Input Password" and numeric keypads will appear. Input the password and press [ENTER].

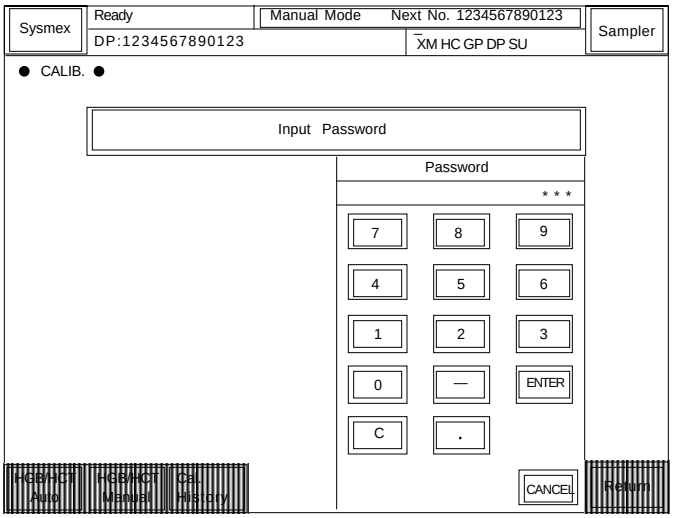

Figure 7-2: Password Input Screen

(3) The HGB/HCT Auto screen containing submenu will appear.

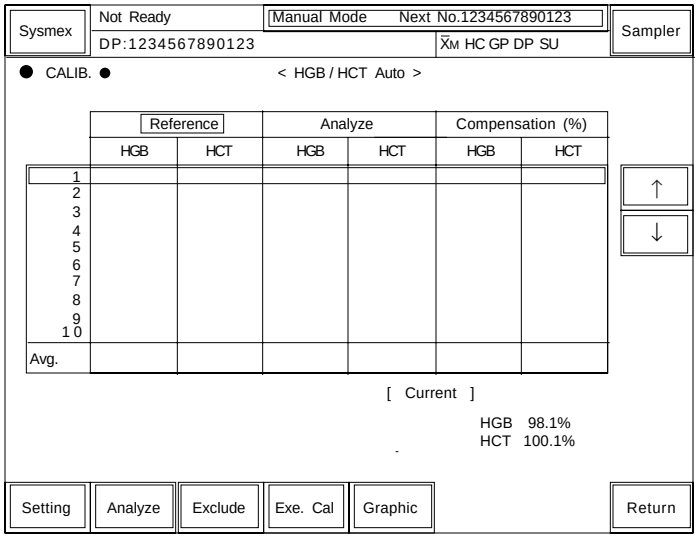

Figure 7-3: HGB/HCT Auto Screen

NOTE: When the HGB/HCT Auto program is in use, the Main Unit READY LED turns off. Normal samples cannot be analyzed at this time.

Submenu Keypads Operation

[Setting] : Enters the reference HGB and HCT values. Refer to the following *Section 2.2 Setting*.

[Analyze] : Analyzes the samples. Refer to *Section 2.3 Analyze*.

[Exclude] : Review data obtained after specimens have been analyzed with this program. Data may be marked and not included in the final calibration calculation. Data selected for exclusion may also be recovered before auto calibration is executed. Refer to *Section 2.4 Exclude*

[Exe.Cal] : Calculates the changes necessary to update the [Current] compensation factors. Data from the difference between reference values and analyzed samples is utilized. Refer to *Section 2.5 Exe.Cal*.

[Graphic] : Displays the scattergrams and particle size distributions of the last sample analyzed. Refer to *Section 2.6 Graphic*.

(4) Press [Return] key. The confirmation message "Exit Auto Cal. OK?" will appear.

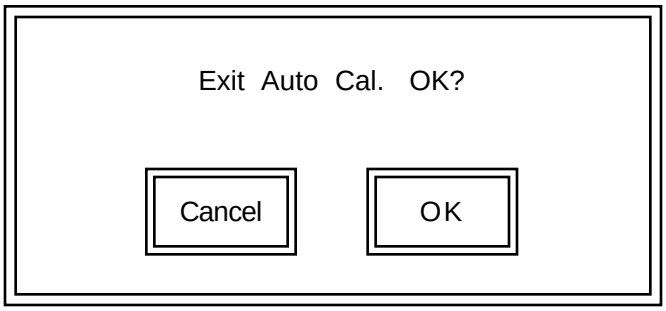

Figure 7-4: Confirmation Message Window

Pressing [OK] erases all data and ends the HGB/HCT Auto program.
Pressing [Cancel] retains the calibration data generated, permitting HGB/HCT Auto program to continue.

2.2 Setting (Entering Reference Values)

To perform HGB/HCT Auto calibration program, you must enter, as the reference values, the measured HGB and HCT values obtained using reference methods. A maximum of 10 sets of data can be registered.

(1) From the HGB/HCT Auto submenu, press [Setting]. "Reference" display will be backlit in blue, and numeric keypads will appear.

(2) Select the "Reference" sample number by using the [↑] and [↓] keys to move the cursor.

Select either "HGB" or "HCT" by using the [←] and [→] keys.

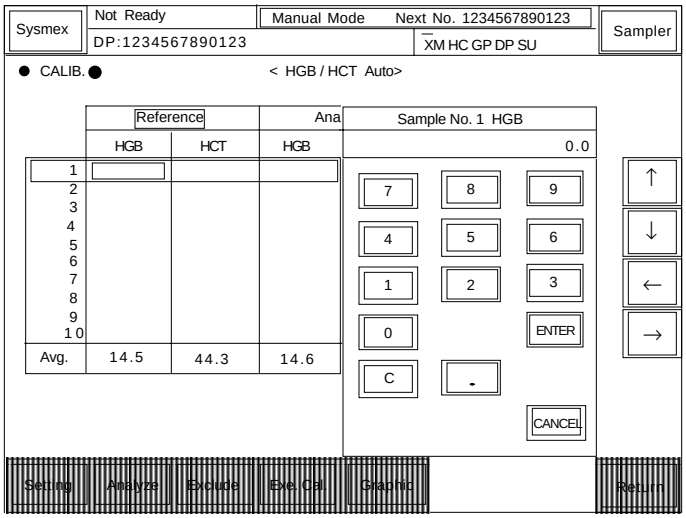

Figure 7-5: HGB/HCT Auto - Setting Screen (1)

(3) Use the numerical keys to enter the HGB/HCT reference values obtained using the reference methods. The input format should correspond with the unit settings. Press [Enter] to move the cursor to the next item.

NOTE: Press the [C] key to delete the entered values.

If at least one reference value for HGB/HCT is entered, the average will automatically be calculated and displayed in the "Avg." column. See Figure 7-6.

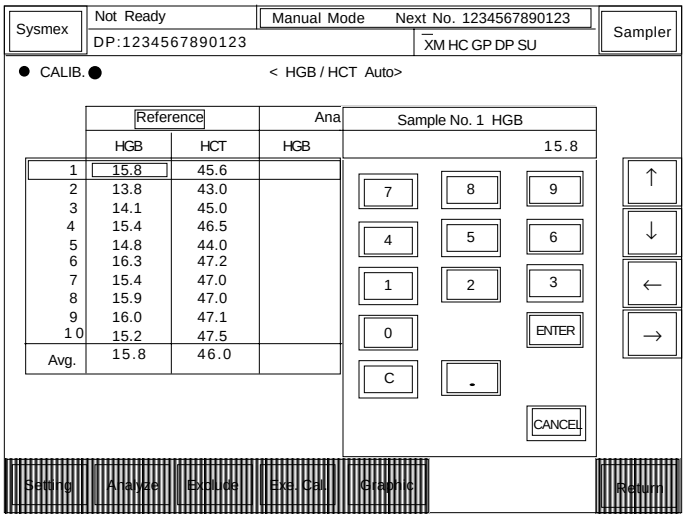

Figure 7-6: HGB/HCT Auto - Setting Screen (2)

If a sample has already been analyzed, the compensation factor will also be automatically calculated. See Figure 7-7.
The calculated compensation factor is displayed in the "Compensation (%)" column. Pressing [Cancel] closes the numeric keypad window and the "Compensation (%)" column appears. Pressing [Setting] key displays the numeric keypads to continue the reference value entry.

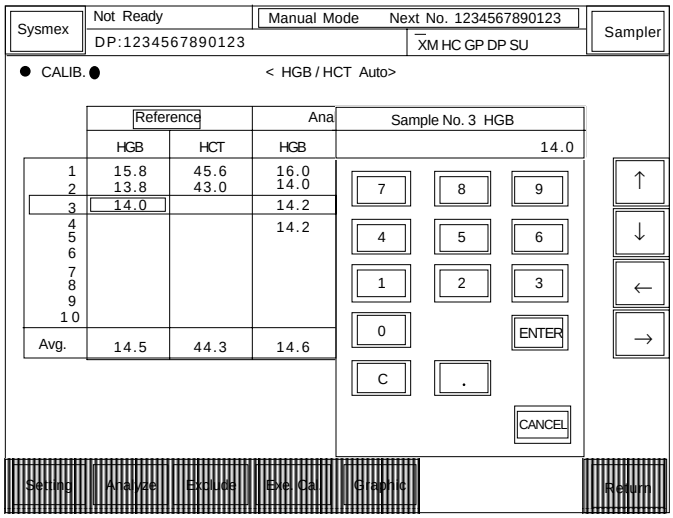

Figure 7-7: HGB/HCT Auto - Setting Screen (3)

NOTE: To update the [Current] compensation factor with the average found in the "Compensation (%)" column, use the "Exe.Cal" program.

2.3 Analyze (Analyzing)

The SF-3000 uses the HGB/HCT Auto submenu program "Analyze" to analyze the reference samples in the Manual mode.

(1) From the HGB/HCT Auto submenu, press [Analyze]. "Analyze" display will be backlit in blue, the main unit READY LED will light and the system will be ready to process samples.

(2) Use the [↑] and [↓] keys to position the cursor on the sample number to be analyzed.

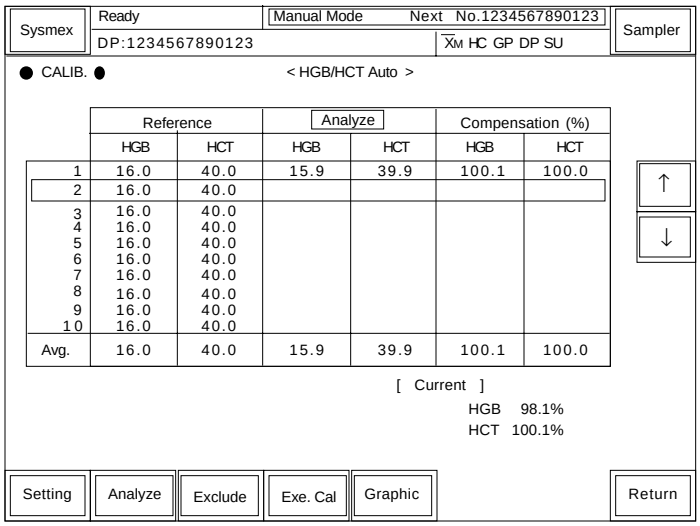

Figure 7-8: Sample Analysis Screen (1)

(3) Analyze the samples using the Manual mode.
During analysis, a blue line appears on the analyzed sample number.
If the [Quit] key on the screen is pressed during analysis, the analysis results are ignored and will not be displayed. Perform analysis again for the sample number.

NOTE: The operator is allowed to reanalyze a sample by moving the cursor to the sample number for which analysis has already been done.

(4) After the analysis is completed, the results will be displayed and the cursor will move to the next sample area.
If at least one HGB/HCT values are obtained, the average will automatically be calculated and displayed in the "Avg." column.
If HGB/HCT reference values have already been entered, the compensation factor will automatically be calculated and displayed in the "Compensation (%)" column.

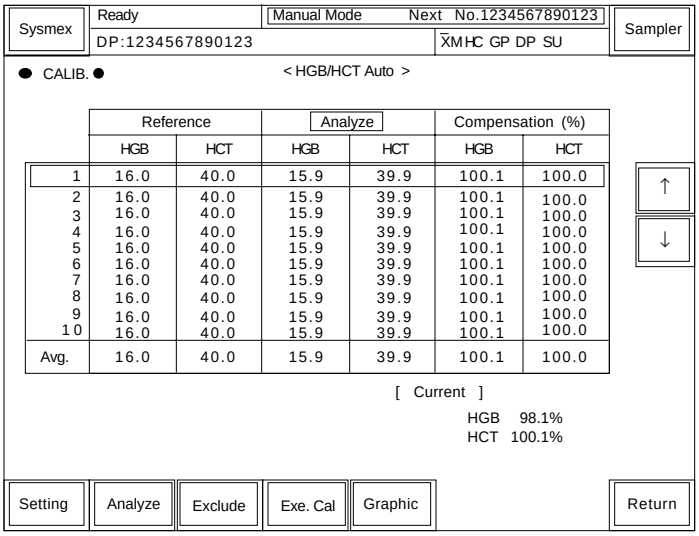

Figure 7-9: Sample Analysis Screen (2)

NOTE: To update the [Current] compensation factor with the average found in the "Compensation (%)" column, use the "Exe.Cal" program.

2.4 Exclude (Excluding and Recovering Data)

Analyzed calibration data whose compensation factor differs significantly from 100% (due to insufficient mixing, analysis error, etc.) may be excluded from the calibration calculation. If necessary, excluded calibration data can also be recovered.

To exclude calibration data:

(1) Use the [↑] and [↓] keys to position the cursor on the calibration data to be excluded from the calculation.

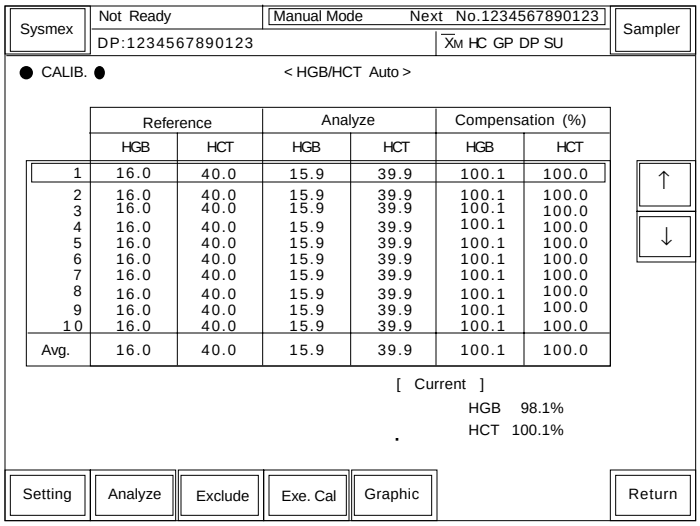

Figure 7-10: Excluding Data Screen (1)

(2) From the HGB/HCT Auto submenu, press [Exclude]. The line is drawn through the calibration data, and the cursor moves to the next sample area. "Reference", "Analyze", and "Compensation (%)" averages are recalculated and displayed.

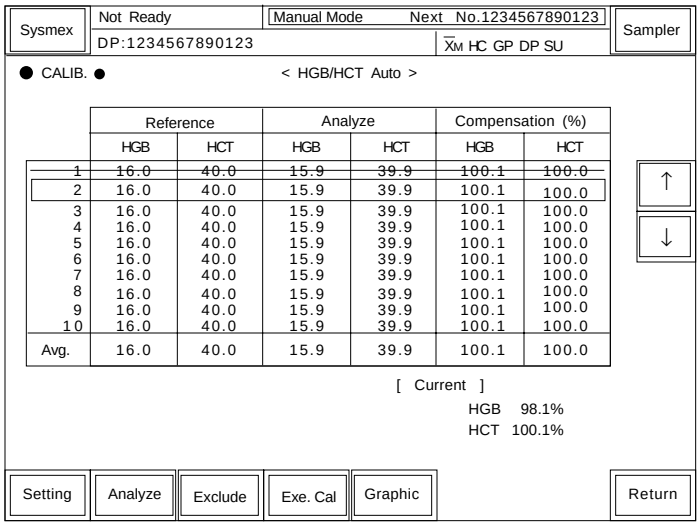

Figure 7-11: Excluding Data Screen (2)

To recover the data:

(1) Use the [↑] and [↓] keys to position the cursor on the calibration data chosen to be restored for use in the calculation.

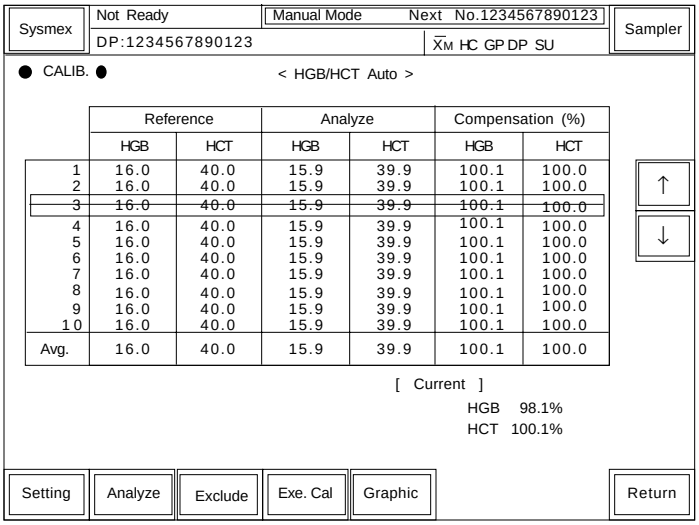

Figure 7-12: Recovering Data Screen (1)

(2) From the HGB/HCT Auto submenu, press [Exclude]. The line drawn through the calibration data disappears, and the cursor moves to the next sample area. "Reference", "Analyze", and "Compensation (%)" averages are recalculated and displayed.

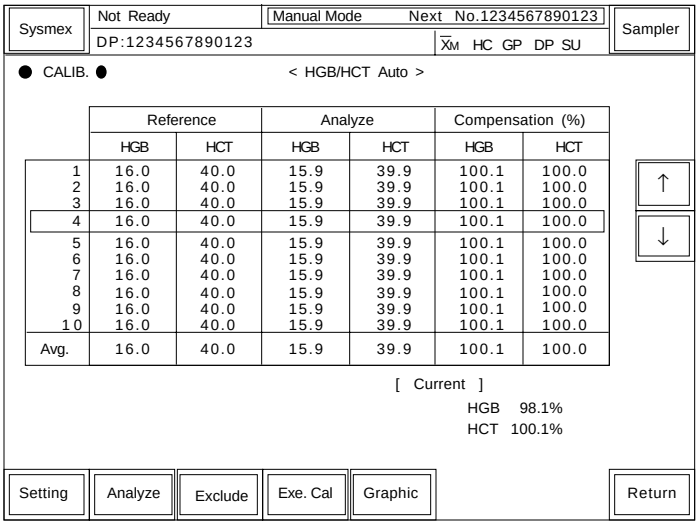

Figure 7-13: Recovering Data Screen (2)

2.5 Exe. Cal. (Calibrating)

New compensation factors are calculated using the averages of the reference and measured values.

NOTE:
- Under [Current], the current compensation factor obtained from the previous calibration is displayed.
- To update the [Current] compensation factor with the average found in the "Compensation (%)" column, use the "Exe.Cal" program.

(1) From the HGB/HCT Auto submenu, press [Exe.Cal]. The message "Execute Calibration" will appear.

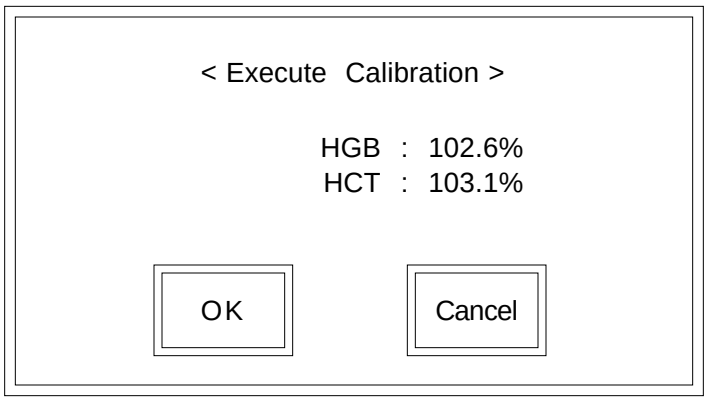

Figure 7-14: Execute Calibration Window

Pressing [OK] key updates the "Current" column by inserting the new compensation factor. The screen returns to the previous display.
Pressing [Cancel] key returns the instrument to the previous screen and permits the HGB/HCT Auto program to continue without updating the calibration values.

NOTE: "Exe.Cal" can be executed only once. However, it can be executed again after a reference value is changed, reanalysis is performed or data is excluded.

New compensation factor is calculated as follows:

$$\text{New Compensation Factor} = \frac{\text{Current comp. factor (\%) x Avg. comp. factor (\%)}}{100}$$

The compensation calculation is not performed if the average compensation factor is 100.0%. Press [Quit] to return to the previous screen, permitting HGB/HCT Auto program to resume.

NOTE:

- The message "Cannot Execute Calibration" will be displayed and the calibration values will not be updated if they are **greater** than the following tolerances:
  - Newly calculated compensation - Current compensation: 5%,
  - Newly calculated compensation: 100 ± 20%
- If any average compensation factor exceeds 100±5% but the newly calculated current compensation factor is within 100±20%, calibration can only be updated using manual calibration. Refer to *Section 3* in this chapter.

(2) Re-analyze the samples designated for calibration. Confirm that the measured values do not differ significantly from the reference values and that they are within the allowable range.

If the HGB/HCT value is consistently higher or lower than the reference value, recalibrate. If the difference continues to exceed the limits, check for sample abnormalities such as coagulation problems, abnormal morphology, patient medication, old blood samples, etc. If no sample abnormalities are discovered, contact your Sysmex service representative.

2.6 Graphic (Displaying Graphs)

(1) From the HGB/HCT Auto submenu, press [Graphic]. The scattergrams and particle size distributions of the last sample analyzed will be displayed.

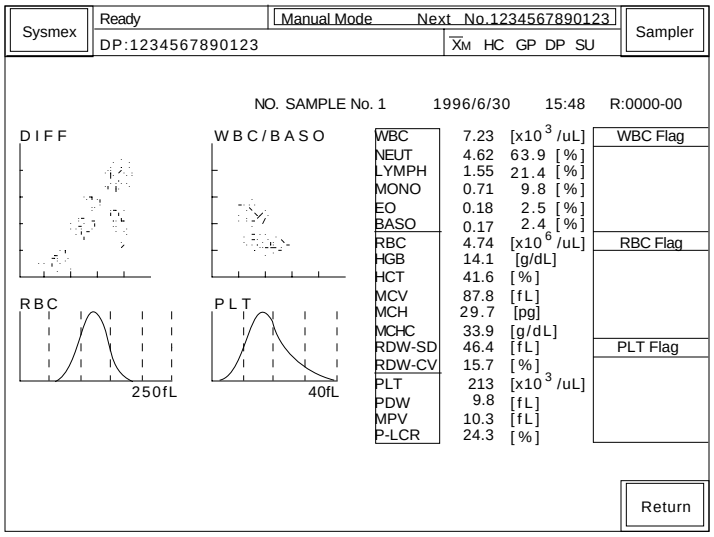

Figure 7-15: Graphic Display Screen

(2) Press [Return] key and the instrument returns to the HGB/HCT Auto screen, permitting Auto Cal. to continue.

3. HGB/HCT MANUAL

HGB and HCT values can also be calibrated manually by entering the updated calibration values using the numerical keys. The compensation factor value changed by the manual calibration program should be within a range of 100±20%. If calibration beyond this range is required, contact the Sysmex service representative.

3.1 Calculating the Compensation Factor

(1) Using the reference method, analyze 5 to 10 samples 3 times each to find the HGB and HCT values.

(2) Thoroughly mix the same samples, then analyze them in the Manual mode.

(3) If there is a difference between the data measured with the SF-3000 and the reference values measured with the reference methods, calculate new compensation factors by using the following formula:

$$\text{New Compensation Value} = \text{Current Compensation Value} \times \frac{\text{Reference mean}}{\text{Instrument mean}}$$

[Example]
Reference HGB mean = 15.6 g/dL
SF-3000 HGB mean = 15.5 g/dL
Current HGB compensation factor = 100.0%

$$100.0 \times \frac{15.6}{15.5} = 100.65 \text{ or } 100.7\% \text{ (rounded)}$$

Therefore, the new compensation factor for HGB should be entered as 100.7%. The compensation factor has increased by 0.7%.

3.2 Executing the HGB/HCT Manual Program

(1) Press [Calib.] keypad in the root menu. The Calibration screen containing submenu will appear.

NOTE: If the [Calib.] keypad is not displayed on the LCD, press [More] to change the root menu display.

(2) Press [HGB/HCT Manual]. The message "Input Password" and numeric keypads will appear. Input the password and press [ENTER].

(3) The current compensation factor is displayed. Use the [↑] and [↓] keys to position the cursor on the desired compensation factor.

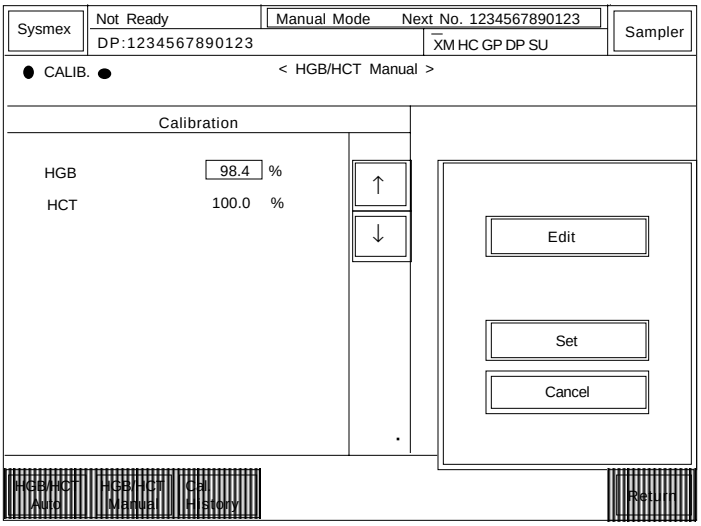

Figure 7-16: HGB/HCT Manual Calibration Screen (1)

(4) Press [Edit] key and the numerical keys are displayed. Enter the calculated compensation factor with the numerical keys.

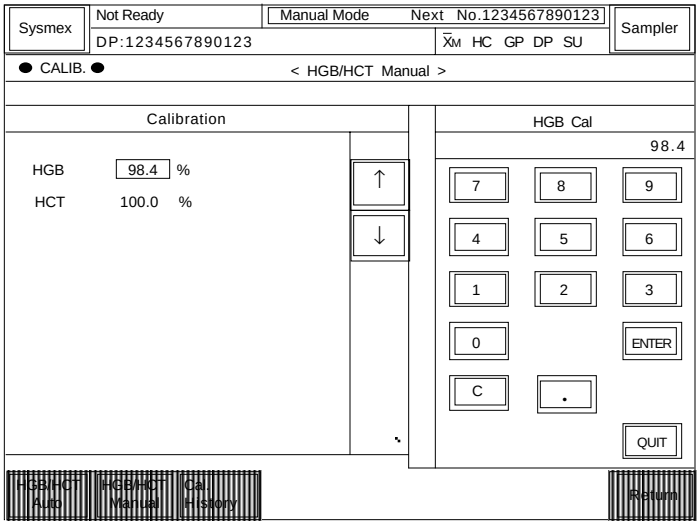

Figure 7-17: HGB/HCT Manual Calibration Screen (2)

Pressing [ENTER] moves the cursor to the next compensation factor.
Pressing [QUIT] closes the numeric key window and returns to the previous screen (shown in Figure 7-16).

(5) Press [Set] to update the compensation factor and end the program.
Press [Cancel] to end the program without updating the compensation factor.
Press [Edit] key to re-enter the calibration value(s).

(6) Re-analyze the samples used in the calibration process. Confirm that the measured values do not differ significantly from the reference values and that they are within the allowable range.

If the HGB/HCT value is consistently higher or lower than the reference value, recalibrate. If the difference continues to exceed the limits, check for sample abnormalities such as coagulation problems, abnormal morphology, patient medication, old blood samples, etc. If no sample abnormalities are discovered, contact your Sysmex service representative.

4. CALIBRATION HISTORY

Up to 10 calibration histories can be accessed from the calibration history file.

4.1 Displaying the Cal. History

(1) Press [Calib.] keypad in the root menu. The Calibration screen containing submenu will appear.

> **NOTE:** If the [Calib.] keypad is not displayed on the LCD, press [More] to change the root menu display.

(2) Press [Cal. History]. The message "Input Password" and numeric keypads will appear. Input the password and press [ENTER].

(3) The history file is displayed. This file displays the dates, time, and HGB/HCT compensation factors of the 10 latest calibrations.

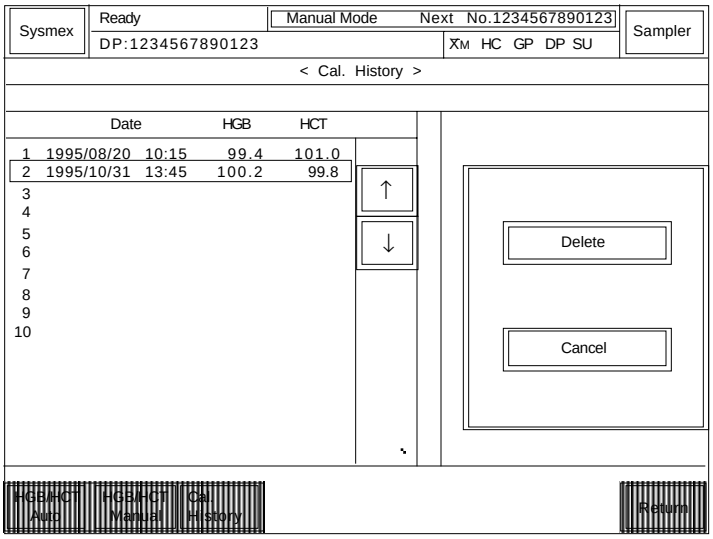

Figure 7-18: Calibration History Screen

4.2 Deleting the Cal. History

Unnecessary calibration histories can be deleted from the calibration history file.

(1) Display the calibration history file.

(2) Use the [↑] and [↓] keys to move the cursor and select the histories to be deleted.

(3) Press [Delete] key. The deletion confirmation message will be displayed.

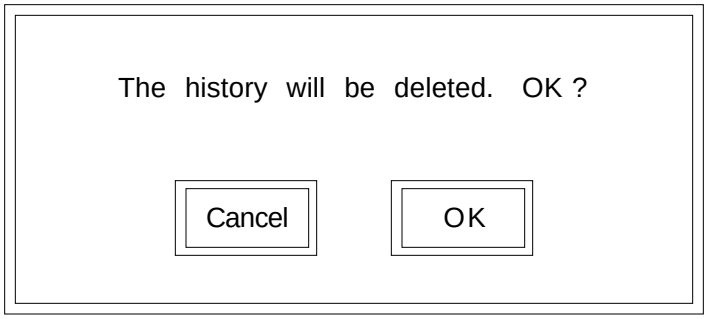

Figure 7-19: Deletion Confirmation Window

(4) Pressing [Cancel] returns to the Calibration History display without deleting the calibration history data.
Pressing [OK] deletes the history.

NOTE: The latest calibration history cannot be deleted.

4.3 Outputting the Cal. History

To obtain the printout of the calibration history, use the "Hard Copy" program as below.

(1) Display the calibration history on the LCD.

(2) Press the [Sysmex] keypad in the upper left corner of the screen. The Sysmex submenu window will appear.

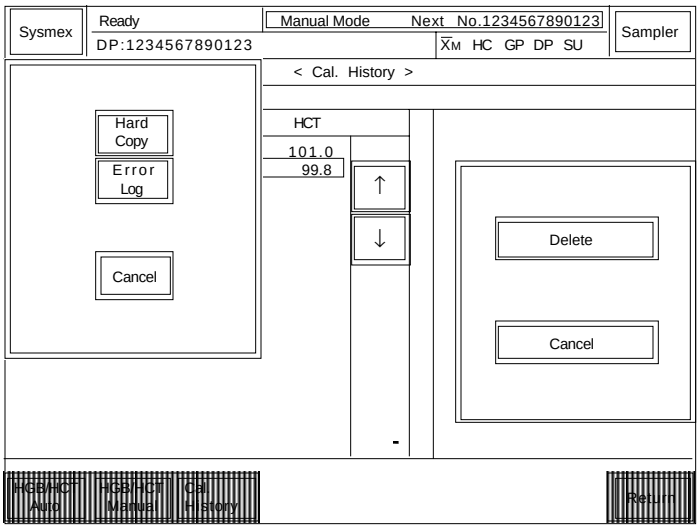

Figure 7-20: Sysmex Submenu Window

(3) Press [Hard Copy] key. The copy of the calibration history display will be output to the Graphic Printer. (Refer to *Chapter 1, Section 9.3: Hard Copy.*)

CHAPTER 8 TROUBLESHOOTING

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1. INTRODUCTION

This chapter contains explanations of the error messages displayed by the SF-3000, when malfunctions occur, and of the countermeasures that the operator can take. Should the countermeasures given in this chapter fail to restore the system to normal condition, contact your Sysmex service representative.

This chapter consists of the following sections:

- Troubleshooting by Error Messages
  This section contains (a) an alphabetical index of all the error messages displayed on the LCD screen when malfunctions occur, and (b) a troubleshooting guide for the problems that may be encountered.

- Maintenance
  This section explains about the programs to run in order to maintain the system and carry out operation tests.

- Status Display
  This section explains about the system status displays.

- Error Log
  This section explains about the program to run in order to obtain displays of error log lists.

2. TROUBLESHOOTING BY ERROR MESSAGES

2.1 Alphabetical Error Message Index

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0.6 kg/cm^2 Error 8-9
2.0 kg/cm^2 Error 8-10
250 mmHg Error 8-10

[A]
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Blood Asp Sensor Error.....8-21

[C]
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Clean the Waste Chamber 8-57
Clean the WBC Detector.....8-58
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Close WBC Detector Cover.....8-37
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Control Table Error 8-46

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[H]
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[M]
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[N]
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[O]
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Replace Reagent Container PK (3).....8-15
Replace Reagent Container SLS.....8-15
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Rinse Motor Function Error.....8-19

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WBC Detector Thermal Sensor Discon.....8-14
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< $\overline{X}$ M Limit Error >..... 8-55

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< Analysis Error > 8-38
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DIFF CCSD Noise Error 8-41
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2.3 Troubleshooting Guide

1. Pressure and Vacuum Errors

0.5 kg/cm^2 Error

Phenomena	0.5 kg/cm^2 pressure dose not reach the required range. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	1) Incorrect adjustment of 0.5 kg/cm^2 pressure 2) 0.5 kg/cm^2 regulator is defective.
Corrective Action	1) Adjust 0.5 kg/cm^2 pressure. (See *Chapter 9, Section 4: Main Unit Adjustment*.) 2) If adjustment of 0.5 kg/cm^2 pressure failed, the regulator is probably defective. Contact your Sysmex service representative.

0.6 kg/cm^2 Error

Phenomena	0.6 kg/cm^2 pressure dose not reach the required range. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	1) Incorrect adjustment of 0.6 kg/cm^2 pressure 2) 0.6 kg/cm^2 regulator is defective.
Corrective Action	1) Adjust 0.6 kg/cm^2 pressure. (See *Chapter 9, Section 4: Main Unit Adjustment*.) 2) If adjustment of 0.6 kg/cm^2 pressure failed, the regulator is probably defective. Contact your Sysmex service representative.

2.0 kg/cm^2 Error

Phenomena	2.0 kg/cm^2 pressure dose not reach the required range. Analysis cannot be continued until the error is resolved.
Probable Cause	1) Incorrect adjustment of 2.0 kg/cm^2 pressure. 2) Inadequate pressure output from the Pneumatic Unit 3) A pressure connection tube has become disconnected.
Corrective Action	1) Adjust Main Unit 2.0 kg/cm^2 pressure (See *Chapter 9, Section 4: Main Unit Adjustment*.) 2) Check the Pneumatic Unit power switch and power cord connection. 3) Check the pressure tubing connection. 4) Check the pressure output by pinching the tubing between the Main Unit and the Pneumatic Unit. If the Pneumatic Unit pressure returns to normal, problem is in Main Unit. 5) If Pneumatic Unit pressure is still low, adjust Pneumatic Unit pressure via relief value. (See *Chapter 9, Section 3: Pneumatic Unit Adjustment*.)

250 mmHg Error

Phenomena	250 mmHg vacuum dose not reach the required range. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	1) Incorrect adjustment of 250 mmHg vacuum 2) There is fluid in the Pneumatic Unit trap chamber. 3) Vacuum line is blocked. 4) Inadequate vacuum output from the Pneumatic Unit
Corrective Action	1) Adjust the 250 mmHg vacuum. (See *Chapter 9, Section 3: Pneumatic Unit Adjustment*.) 2) Check the Pneumatic Unit trap chamber for liquid. If present, discard the liquid and reassemble. Be sure the trap chamber is securely attached. (See *Chapter 5, Section 3.2: Remove Fluid from Pneumatic Unit Trap Chamber*.) 3) Check the vacuum tubing connection. 4) Check the vacuum output by pinching the tubing between the Main Unit and the Pneumatic Unit. If the Pneumatic Unit vacuum returns to normal, problem is in Main Unit. 5) Clean the vacuum orifice. (See *Chapter 5, Section 5.1: Clean Orifice*.)

Pressure Lower Error

Phenomena	2.0 kg/cm^2 pressure suddenly decreases below 1.5 kg/cm^2. The system terminates the operation and the "Turn Off Power" message appears.
Probable Cause	1) The Pneumatic Unit is suddenly powered off during operation. 2) The fuse for pneumatic unit protection is blown. 3) A pressure connection tube has become disconnected. 4) Solenoid valve is defective.
Corrective Action	1) Turn OFF the power of the Main Unit. 2) Check the Pneumatic Unit power switch and power cord connection. 3) Check the pressure tubing connection. 4) Check the fuse, and replace if blown off. (See *Chapter 5, Section 8.7: Replace the Fuses*.) 5) Turn ON the power of the Main Unit. 6) If the hand clipper has grasped a blood collection tube when this error occurred, remove the piercer cover and return the collection tube to its original position in the Sample Rack. Upon correcting the error the operator will need to reset the rack. 7) If the error persists after the power ON, contact Sysmex service representative.

2. Temperature Errors

RBC Detector Temp High
RBC Detector Temp Low

Phenomena	Temperature of RBC detector is outside the required range. An analysis error may occur, and the "Check Stored Data" message also appears. When the sample analysis being processed is completed, the system returns to the Ready.
Probable Cause	1) The temperature in the unit has not reached the required range after power ON. 2) Ambient temperature is too high or too low. 3) Thermistor is defective.
Corrective Action	1) Wait until temperature is stabilized to the required range. If this error is still displayed 30 minutes after the power on, contact Sysmex service representative. 2) Control the room temperature within the range of 15 - 30°C.

Reaction Chamber Temp High
Reaction Chamber Temp Low

Phenomena	Temperature of WBC Reaction Chamber is outside the required range. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	1) The temperature in the unit has not reached the required range after power ON. 2) Thermistor is defective.
Corrective Action	1) Wait until temperature has stabilized to the required range. If this error is still displayed 30 minutes after the power on, contact Sysmex service representative.

Sheath Heater Temp High
Sheath Heater Temp Low

Phenomena	Temperature of Sheath Heater is outside the required range. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	1) The temperature in the unit has not reached the required range after power ON. 2) Thermistor is defective.
Corrective Action	1) Wait until temperature is stabilized to the required range. If this error is still displayed 30 minutes after the power on, contact Sysmex service representative.

WBC Detector Temp High
WBC Detector Temp Low

Phenomena	Temperature of WBC detector is outside the required range. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	1) The temperature in the unit has not reached the required range after power ON. 2) Thermistor is defective.
Corrective Action	1) Wait until temperature has stabilized to the required range. If this error is still displayed 30 minutes after the power on, contact Sysmex service representative.

React Chamber Thermal Sensor Discon.

Phenomena	The thermal sensor monitoring the WBC reaction chamber is defective. Analysis cannot be performed until the error is resolved.
Probable Cause	The thermal sensor monitoring the WBC reaction chamber is defective or cut.
Corrective Action	1) In the auto mode analysis, reset the rack and press [Sampler], then [Start] to resume analysis. 2) If the error persists, the thermal sensor replacement may be necessary. Contact your Sysmex service representative.

Sheath Heater Thermal Sensor Discon.

Phenomena	The thermal sensor monitoring the sheath heater is defective. Analysis cannot be performed until the error is resolved.
Probable Cause	The thermal sensor monitoring the sheath heater is defective or cut.
Corrective Action	1) In the auto mode analysis, reset the rack and press [Sampler], then [Start] to resume analysis. 2) If the error persists, the thermal sensor replacement may be necessary. Contact your Sysmex service representative.

WBC Detector Thermal Sensor Discon.

Phenomena	The thermal sensor monitoring the WBC detector is defective. Analysis cannot be performed until the error is resolved.
Probable Cause	The thermal sensor monitoring the WBC detector is defective or cut.
Corrective Action	1) In the auto mode analysis, reset the rack and press [Sampler], then [Start] to resume analysis. 2) If the error persists, the thermal sensor replacement may be necessary. Contact your Sysmex service representative.

3. Chamber Errors

Replace Reagent Container FDO
Replace Reagent Container FDT
Replace Reagent Container FBA
Replace Reagent Container SLS

Replace Reagent Container PK (1)
Replace Reagent Container PK (2)
Replace Reagent Container PK (3)

NOTE: There are three reservoir chambers for CELLPACK (PK-30L); PK1, PK2 and PK3. For the servicing convenience purpose, the messages above for PK replacement contains the chamber number as PK (1) indicating the CELLPACK Chamber PK1 may contain insufficient reagent. Replace the CELLPACK container and follow the instructions below when any of these three messages appear.

Phenomena	Sufficient reagent(s) for analysis is not aspirated. Analysis cannot be performed until the error is resolved.
Probable Cause	1) There is insufficient reagent. 2) Abnormality in the hydraulic system 3) Float switch is defective.
Corrective Action	1) Replace the reagent container(s) and press [Replace Reagent] in the root menu. (See *Chapter 5, Section 8.1: Replace Reagent*.) 2) Check the hydraulic system for looseness, tears, or disconnection of the nipple(s) and tube(s) for the reagent(s) indicated by the error message. If there is abnormality, repair or replace the affected items. 3) If the error persists, contact Sysmex service representative. Only when it is requested by the service representative, open the left side cover and check the float switch(es) and tubing visually with his/her assistance. Refer to Figure 8-1 on the next page.

WARNING! The hydraulic system should be considered potentially biohazardous. Do not handle the tubing or chambers without proper protective equipment. Wear rubber gloves when checking the hydraulic system. Wash your hands with an antiseptic solution after completing the procedure.

CAUTION: DO NOT open the Main Unit left side cover without direction or assistance of Sysmex service representative.

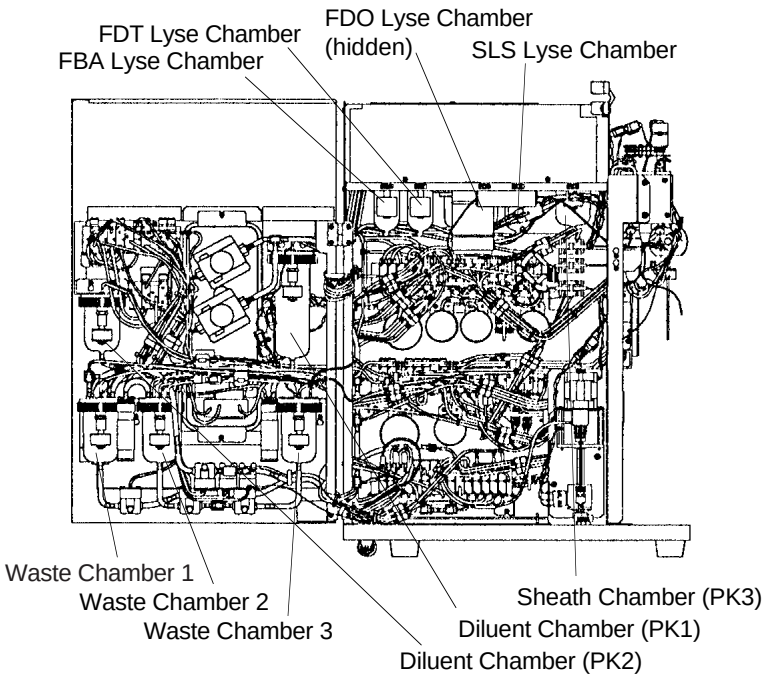


Figure 8-1: Chambers Location (Main Unit - Left Interior)

Waste Chamber 1 Not Draining
Waste Chamber 2 Not Draining
Waste Chamber 3 Not Draining

Phenomena	The waste in the waste chamber cannot be drained. Analysis cannot be performed until the error is resolved.
Probable Cause	1) Bent, kinked, or blocked drain line tubing 2) Defective float switch or sensor inside the waste chamber 3) Defective solenoid valve
Corrective Action	1) Check the waste line tubing and nipple on the rear panel of the instrument. If the tube connected to the waste drain nipple is bent, kinked, or blocked, clean or replace it. If no blockage is found and if the error is resolved after a while, it is assumed that the dirt is accumulated inside the tubing. To clean the tubing, execute waste chamber cleaning sequence. Refer to *Chapter 5, Section 5.2: Execute Clean Waste Chamber Sequence*. 2) If the error persists, contact Sysmex service representative. Only when it is requested by the service representative, open the left side cover and check the float switch(es) and tubing visually with his/her assistance. (See Figure 8-1 for chamber location.) Pay special attention to dirt and blockage around the drain outlet nipple within the waste chamber.

WARNING! The hydraulic system should be considered potentially biohazardous. Do not handle the tubing or chambers without proper protective equipment. Wear rubber gloves when checking the hydraulic system. Wash your hands with an antiseptic solution after completing the procedure.

CAUTION: DO NOT open the Main Unit left side cover without direction or assistance of Sysmex service representative.

4. Motor Errors

Sheath Motor Function Error

Phenomena	Sheath injector piston driving motor did not move properly, and the movement of the sheath injector piston stopped. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	The resistance on the sheath injector piston is abnormally high.
Corrective Action	1) Execute the sheath motor test program. (Refer to *Section 3.3: Test Motor* in this chapter.) 2) If the error persists after the test program is completed, turn the Main Unit power OFF, then ON again. 3) If the error still persists, contact your Sysmex service representative. Only when it is required by the service representative, open the left side cover and check visually with his/her assistance to make sure that no fluid connector or tubing is touching the sheath injector piston upper/lower parts.

WARNING! The hydraulic system should be considered potentially biohazardous. Do not handle the tubing or chambers without proper protective equipment. Wear rubber gloves when checking the hydraulic system. Wash your hands with an antiseptic solution after completing the procedure.

CAUTION: DO NOT open the Main Unit left side cover without direction or assistance of Sysmex service representative.

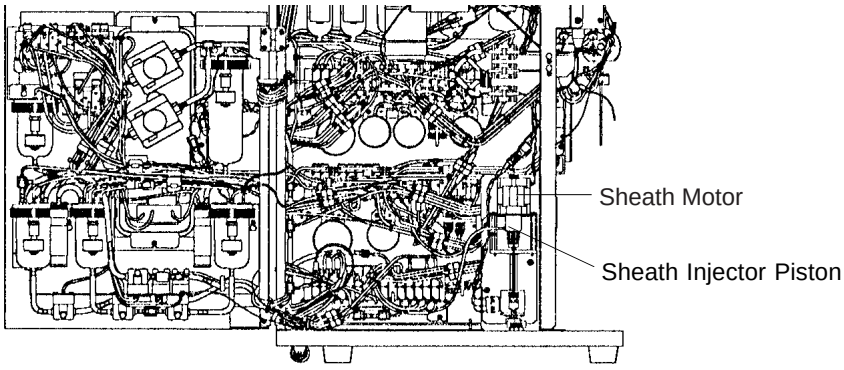


Figure 8-2: Sheath Injector Piston Location (Main Unit - Left Interior)

Rinse Motor Function Error

Phenomena	Manual rinse mechanism driving motor did not move properly, and the movement of the manual rinse mechanism stopped. Analysis cannot be continued until the error is resolved.
Probable Cause	The resistance on the manual rinse mechanism is abnormally high.
Corrective Action	1) Check visually to make sure that no fluid connector or tubing is touching the manual rinse mechanism upper/lower parts. 2) Check the rinse motor operation using test program. (Refer to *Section 3.3: Test Motor* in this chapter.) 3) If the error persists after the test program is completed, turn the Main Unit power OFF, then ON again. 4) If the error still persists, contact your Sysmex service representative.

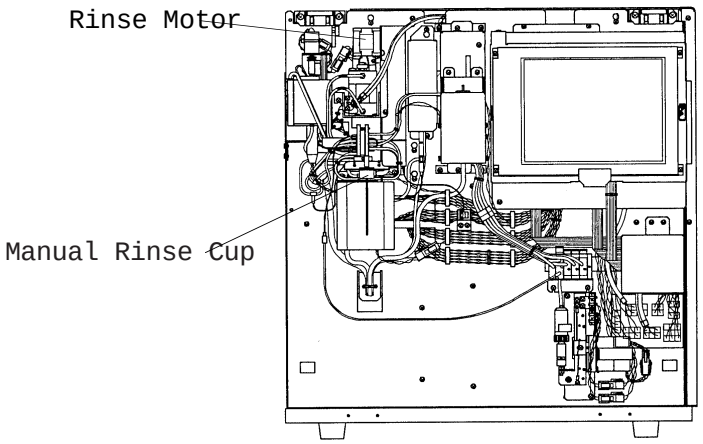


Figure 8-3: Rinse Motor Location (Main Unit - Front Interior)

WB Asp Motor Function Error

Phenomena	Whole blood aspiration pump driving motor did not move properly, and the movement of the whole blood aspiration pump stopped. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	The resistance on the whole blood aspiration pump is abnormally high.
Corrective Action	1) Check the WB Asp motor operation using test program. (Refer to *Section 3.3: Test Motor* in this chapter.) 2) If the error persists after the test program is completed, turn the Main Unit power OFF, then ON again. 3) If the error still persists, contact your Sysmex service representative.

Mixing Motor Speed Error

Phenomena	WBC reaction chamber mixing motor does not move properly. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	1) The bearing of the mixing motor is dirty. 2) The belt of the mixing motor is damaged. 3) Mixing motor is incorrectly adjusted.
Corrective Action	1) Check the motor rotation speed using test program. (Refer to *Section 3.3: Test Motor* in this chapter.) 2) Replace the mixing motor belt. (Refer to *Chapter 5, Section 8.8: Replace the Belt No. 6.*) 3) If the error still persists, contact your Sysmex service representative.

5. Whole Blood Aspiration and Dilution Errors

Blood Asp Sensor Error

Phenomena	The blood aspiration sensor does not function normally. The sample is not processed, and data is reported by "----" as an analysis error. If the system is set to be stopped by this error, the system will be STAT ready for the sample analysis in manual or capillary mode. If the system is set to continue analysis when this error occurs, the system will process the next sample.
Probable Cause	Blood aspiration sensor, that monitors whether blood is being aspirated normally during sampler operation, is defective.
Corrective Action	1) Replace the blood aspiration sensor. Contact your Sysmex service representative to replace it. 2) As a tentative measure, change the Sampler Stop Conditions to allow sampler operation to continue. Refer to *Chapter 11, Section 3.4: Sampler Stop Condition*.

Low Blood Volume

Phenomena	This error occurs during auto mode or manual closed mode analysis only. The sample is not processed, and data is reported by "----" as an analysis error. The "Check Stored Data" message also appears. If the system is set to be stopped by this error, the system will be STAT ready for the sample analysis in manual or capillary mode. If the system is set to continue analysis when this error occurs, the system will process the next sample.
Probable Cause	Insufficient sample volume is prepared for analysis using sampler unit.
Corrective Action	1) Re-analyze the sample in manual or capillary mode, if required. 2) When the system is stopped for analysis of the error sample, process the sample in manual or capillary mode; then press [Sampler] - [Start] keypads to resume the sampler operation for the next sample.

Sample Not Asp Error

Phenomena	This error occurs during auto mode or manual closed mode analysis only. Sufficient blood sample volume was not aspirated. (One sensor at SRV cannot detect the sample blood.) The sample is not processed, and data is reported by "----" as an analysis error. The "Check Stored Data" message also appears. If the system is set to be stopped by this error, the system will be STAT ready for the sample analysis in manual or capillary mode. If the system is set to continue analysis when this error occurs, the system will process the next sample.
Probable Cause	1) Abnormal blood sample • Clumps present in blood sample • Extremely low concentration of blood 2) Bent, blocked or defective piercer needle, SRV and/or sampler whole blood aspiration tubing 3) Aspiration tubing is disconnected from the sampler or the SRV.
Corrective Action	1) Check the blood sample visually, and repeat the analysis. If the blood sample is of extremely low concentration (HGB < 3.0 g/dL), analyze the sample in the manual mode. 2) Check and if the whole blood aspiration tube is disconnected, reconnect. 3) Check piercer, SRV and whole blood aspiration line. Clean them as follows: (a) Perform the shutdown sequence using CELLCLEAN (or 5% filtered sodium hypochlorite). Refer to *Chapter 5, Section 3.1: Shutdown*. (b) When the shutdown sequence is complete, press [Auto Rinse] key to check the background count. When the background check is complete and system enters Ready, reanalyze the sample. (c) If the error persists, aliquot CELLCLEAN into 3 collection tubes and analyze these samples in the auto mode to clean the piercer and the whole blood aspiration line. (d) If the error still persists, it is assumed that the piercer is blocked by clots. Replace the piercer. Refer to *Chapter 5, Section 8.2: Replace the Piercer*.

Short Sample

Phenomena	This error occurs during auto mode or manual closed mode analysis only. Sufficient blood sample volume was not aspirated. (Two sensors at SRV cannot detect the sample blood.) The sample is not processed, and data is reported by "----" as an analysis error. The "Check Stored Data" message also appears. If the system is set to be stopped by this error, the system will be STAT ready for the sample analysis in manual or capillary mode. If the system is set to continue analysis when this error occurs, the system will process the next sample.
Probable Cause	1) Blood volume is insufficient. 2) Piercer needle and/or whole blood aspiration line is dirty.
Corrective Action	1) Check the blood sample volume. If the blood sample volume is short, analyze it in manual or capillary mode. 2) If the error persists although there is enough sample in the collection tube, it is suspected that the piercer or the whole blood aspiration line is dirty. Clean them as follows: (a) Perform the shutdown sequence using CELLCLEAN (or 5% filtered sodium hypochlorite). Refer to *Chapter 5, Section 3.1: Shutdown*. (b) When the shutdown sequence is complete, press [Auto Rinse] key to check the background count. When the background check is complete and system enters Ready, reanalyze the sample. (c) If the error persists, aliquot CELLCLEAN into 3 collection tubes and analyze these samples in the auto mode to clean the piercer and the whole blood aspiration line. (d) If the error still persists, it is assumed that the piercer is blocked by clots. Replace the piercer. Refer to *Chapter 5, Section 8.2: Replace the Piercer*.

NOTE: Sometimes the sample volume cannot be monitored by the Sampler Unit because the blood collection tube is dirty or because the bar code label has been affixed too low. In such cases, aspiration is performed anyway, and if the volume is insufficient, "Short Sample" or "Sample Not Asp Error" will occur.

SRV Initial Position Error
SRV Move Position Error
SRV Move Too Slow

Phenomena	The SRV does not move to the specified position. Analysis cannot be continued until the error is resolved. When SRV Initial/Move Position Errors occur, an analysis error is reported, and the "Check Stored Data" message also appears.
Probable Cause	1) SRV operation is faulty; not in the initial position, not in the moved position, or takes too much time to reach the specified position. 2) SRV is dirty.
Corrective Action	1) Check to make sure that no tubing is touching any of the sampling valve rotating part. 2) Perform SRV test operation. (Refer to *Section 3.2: Test SRV* in this chapter.) 3) Clean the SRV. (Refer to *Chapter 5, Section 5.3: Clean SRV.*) 4) If the error persists, turn the Main Unit power OFF, then ON again. 5) If the error still persists, contact Sysmex service representative.

6. Sampler Operation Errors

The names and positions of the various sensors fitted to the Sampler are shown below.

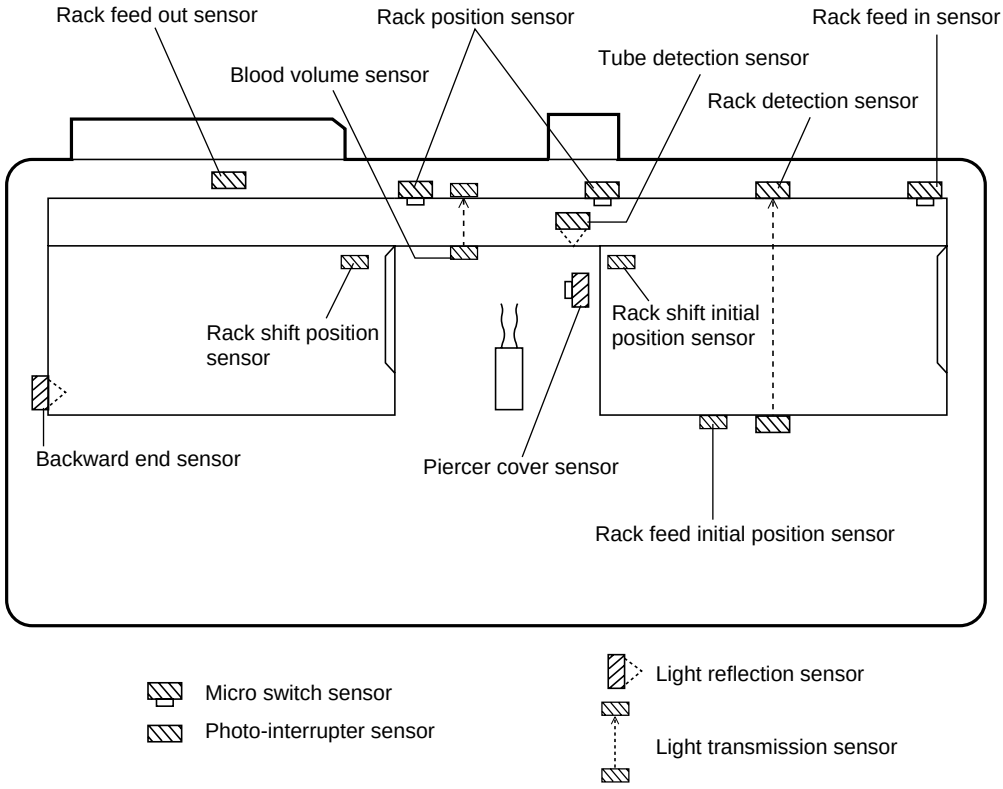


Figure 8-4: Sampler Unit Sensors

Set Piercer Cover

Phenomena	The piercer unit cover on the sampler is not installed. The sample being processed will be completed. After that, sampler operation cannot be continued until the error is resolved, however, manual analysis is possible.
Probable Cause	1) The piercer unit cover on the sampler is not properly installed. 2) Piercer cover sensor is defective.
Corrective Action	1) Install the piercer unit cover. 2) Perform the CP mechanism operation test. Refer to *Section 3.6: Test Sampler* in this chapter. 3) If error persists, contact your Sysmex service representative.

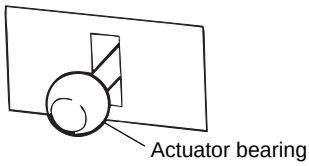
Rack Feed In Function Error

Phenomena	A sample rack cannot be forwarded to the measurement line properly. (The rack feed in function sensor does not turn ON within preset time limit.) The sample being processed will be completed. After that, sampler operation cannot be continued until the error is resolved, however, manual analysis is possible. The "Reset Rack" error message also appears.
Probable Cause	1) Blood, etc. has interfered with the rack feed in function sensor. 2) A foreign object is in the right rack pool blocking the sensor or rack. 3) Rack jammed or was picked up. 4) The rack feed in function sensor is defective.
Corrective Action	1) Remove dirt. 2) Remove all foreign objects from the right rack pool. 3) Reset the rack in the right rack pool and press [Sampler], then [Start] key to resume the analysis. 4) If the error persists, contact your Sysmex service representative.

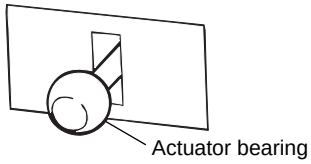
Rack Feed In Home Pos. Error

Phenomena	A sample rack cannot be forwarded to the measurement line properly. (The rack feed in home position sensor does not turn ON within preset time limit.) The sample being processed will be completed. After that, sampler operation cannot be continued until the error is resolved, however, manual analysis is possible. The "Reset Rack" error message also appears.
Probable Cause	1) Blood, etc. has interfered with the rack feed in function sensor. 2) The rack feed in home position sensor is defective.
Corrective Action	1) Remove dirt. 2) Check the rack feed in operation using test program. (Refer to *Section 3.6: Test Sampler* in this chapter.) 3) If the error persists after the test program is completed, turn the Main Unit power OFF, then ON again. 4) If the error still persists, contact your Sysmex service representative.

Rack Shift Function Error

Phenomena	A sample rack did not shift in the measurement line properly. (The rack shift function sensor does not turn ON within preset time limit.) The "Reset Rack" error message also appears. After the sample being processed is completed, the system returns to Ready.
Probable Cause	1) Rack movement was incorrect or incomplete. 2) Blood, etc. has interfered with the rack shift function sensor. 3) Actuator bearing of the rack position sensor is stuck.  4) The rack shift function sensor is defective.
Corrective Action	1) Check that nothing is obstructing rack movement, and remove any dirt or foreign material from the rack moving area. 2) Apply lubricant to bearing. 3) Reset the rack in the right rack pool and press [Sampler], then [Start] key to resume the analysis. 4) If the error persists, contact your Sysmex service representative.

Rack Shift Home Pos. Error

Phenomena	A sample rack did not shift in the measurement line properly. (The rack shift home position sensor does not turn ON within preset time limit.) The "Reset Rack" error message also appears. After the sample being processed is completed, the system returns to Ready.
Probable Cause	1) Rack movement was incorrect or incomplete. 2) Blood, etc. has interfered with the rack shift home position sensor. 3) Actuator bearing of the rack position sensor is stuck.  4) The rack shift home position sensor is defective.
Corrective Action	1) Check that nothing is obstructing rack movement, and remove any dirt or foreign material from the rack moving area. 2) Apply lubricant to bearing. 3) Reset the rack in the right rack pool and press [Sampler], then [Start] key to resume the analysis. 4) If the error persists, contact your Sysmex service representative.

Rack Removed

Phenomena	The sample rack is moved when the hand clipper is holding a collection tube. Sampler operation cannot be continued until the error is resolved, however, manual analysis is possible.
Probable Cause	1) The sample rack is moved when the hand clipper is holding a collection tube. 2) Rack position sensor(s) are defective.
Corrective Action	1) Remove the CP cover and return the collection tube to its original position in the rack. 2) Check the rack shift operation using test program. (Refer to *Section 3.6: Test Sampler* in this chapter.) 3) If the hand clipper has grasped a blood collection tube when this error occurred, remove the piercer cover and return the collection tube to its original position in the Sample Rack. Upon correcting the error the operator will need to reset the rack. 4) Reset the rack and press [Sampler], then [Start] key to resume the analysis. 5) If the error persists, contact your Sysmex service representative.

Rack Move Error 1

Phenomena	A sample rack did not shift although the rack shift motor normally functioned. The "Reset Rack" message also appears. When the sample being processed is completed, the system returns to Ready.
Probable Cause	1) Rack shift lever does not function properly. 2) Rack position sensor(s) are defective.
Corrective Action	1) Reset the rack and press [Sampler], then [Start] key to resume the analysis. 2) If the error still persists, contact your Sysmex service representative.

Rack Move Error 2

Phenomena	A sample rack moved in the measurement line when the rack should not be shifted. The "Reset Rack" message also appears. When the sample being processed is completed, the system returns to Ready.
Probable Cause	1) Rack was moved at incorrect timing. 2) Rack position sensor(s) are defective.
Corrective Action	1) The Reset the rack and press [Sampler], then [Start] key to resume the analysis. 2) If the error still persists, contact your Sysmex service representative.

Rack Move Error 3

Phenomena	A sample rack moved in the measurement line when STAT ready. The "Reset Rack" message also appears. When the sample being processed is completed, the system returns to Ready.
Probable Cause	1) Rack was moved when the instrument is ready for STAT analysis. 2) Rack position sensor(s) are defective.
Corrective Action	1) Reset the rack and press [Sampler], then [Start] key to resume the analysis. 2) If the error still persists, contact your Sysmex service representative.

Rack Feed Out Function Error
Rack Feed Out Home Pos. Error

Phenomena	A sample rack was not forwarded from the measurement line into the left rack pool correctly. When the sample being processed is completed, the system returns to Ready.
Probable Cause	1) Dirt adhering to the shift end sensor. 2) Foreign object is in the left rack pool, blocking movement of the rack. 3) Rack shift end sensor is defective.
Corrective Action	1) Dirt adhering to the shift end sensor. 2) Foreign object is in the left rack pool, blocking movement of the rack. 3) Reset the rack and press [Sampler], then [Start] key to resume the analysis. 4) If the error still persists, contact your Sysmex service representative.

Hand Initial Position Error
Hand Move Position Error

Phenomena	Hand clipper did not move forward and backward correctly. The sample being processed is completed. After that the sampler operation cannot be continued until the error is resolved, however, manual analysis is possible.
Probable Cause	1) Malfunction of the piercer unit back/forward cylinder operation. 2) Hand clipper forward and backward position detection sensor(s) are defective.
Corrective Action	1) If the hand clipper has grasped a blood collection tube when this error occurred, remove the piercer cover and return the collection tube to its original position in the rack. 2) Check the CP mechanism operation using test program. (Refer to *Section 3.6: Test Sampler* in this chapter.) 3) If the error persists after the test program is completed, turn the Main Unit power OFF, then ON again. 4) If the error still persists, contact your Sysmex service representative.

Hand Upper Position Error
Hand Lower Position Error

Phenomena	Hand clipper does not move up down correctly. Sampler operation cannot be continued until the error is resolved.
Probable Cause	1) Malfunction of the piercer unit up/down cylinder operation. 2) ID label is affixed on the collection tube incorrectly. 3) Hand clipper up and down position detection sensor(s) are defective.
Corrective Action	1) Check the label on tube for correct positioning and specifications. 2) Check that nothing is obstructing hand clipper movement. 3) If the hand clipper has grasped a blood collection tube when this error occurred, remove the piercer cover and return the collection tube to its original position in the rack. 4) Check the CP mechanism operation using test program. (Refer to *Section 3.6: Test Sampler* in this chapter.) 5) If the error persists after the test program is completed, turn the Main Unit power OFF, then ON again. 6) If the error still persists, contact your Sysmex service representative.

Tube Invert Position Error

Phenomena	The collection tube was not inverted correctly for piercing. The sample being processed is completed. After that, sampler operation cannot be continued until the error is resolved, however, manual analysis is possible.
Probable Cause	1) Malfunction of the piercer unit up/down cylinder operation. 2) ID label is affixed on the collection tube incorrectly. 3) Tube clamp sensor is defective.
Corrective Action	1) Check the label on tube for correct positioning and specifications. 2) Check that nothing is obstructing hand clipper mixing movement. 3) Remove the piercer cover and return the collection tube to its original position in the rack. 4) Check the CP mechanism operation using test program. (Refer to *Section 3.6: Test Sampler* in this chapter.) 5) If the error persists after the test program is completed, turn the Main Unit power OFF, then ON again. 6) If the error still persists, contact your Sysmex service representative.

Tube Sensor Error

Phenomena	The blood volume sensor judges a sample "present" while the tube detection sensor judges a sample "absent". Sampler operation is continued.
Probable Cause	1) Dirt has interfered with the blood volume sensor. 2) The blood volume sensor is defective.
Corrective Action	1) Remove dirt from the blood volume sensor. 2) If the error persists, contact your Sysmex service representative.

Tube Clamp Error

Phenomena	Hand clippers cannot grasp a collection tube correctly for piercing. The sample being processed is completed. After that, sampler operation cannot be continued until the error is resolved, however, manual analysis is possible.
Probable Cause	1) Hand clipper is bent. 2) ID label is affixed on the collection tube incorrectly. 3) The tube clamp detection sensor is defective.
Corrective Action	1) Check label on tube for correct positioning and specifications. 2) Straighten the hand clipper, or replace it if necessary. Refer to *Chapter 5, Section 8.4: Replace the Hand Clipper"*.) 3) Check the CP mechanism operation using test program. (Refer to *Section 3.6: Test Sampler* in this chapter.) 4) If the error persists after the test program is completed, turn the Main Unit power OFF, then ON again. 5) If the error still persists, contact your Sysmex service representative.

Rack Full Error

Phenomena	Rack have filled up the left rack pool area. Sampler operation cannot be continued until the error is resolved.
Probable Cause	1) Racks have filled up the left rack pool. 2) Foreign object is in the left rack pool blocking the rack full sensor. 3) The rack full sensor is dirty or defective.
Corrective Action	1) Remove the racks or any foreign objects from the left rack pool. 2) Remove dirt. 3) If the error still persists, contact your Sysmex service representative.

Sampler Start Error (Blood Sensor)
Sampler Start Error (Sensor 4)
Sampler Start Error (Sensor 5)

Phenomena	A sample rack is placed in the mid of measurement line when [Sampler], then [Start] key is pressed. The "Reset Rack" message also appears.
Probable Cause	1) Incorrect positioning of sample rack. 2) Tube position sensor(s), blood volume sensor and/or tube detection sensor is defective.
Corrective Action	1) Reset the rack and press [Sampler], then [Start] key to resume analysis. 2) If the error persists, contact your Sysmex service representative.

Rack Not Exist

Phenomena	Rack detection sensor does not detect any rack in the right rack pool when [Sampler], then [Start] key is pressed. The "Reset Rack" message also appears.
Probable Cause	1) No rack is set in the right rack pool when [Sampler], then [Start] is pressed. 2) Rack detection sensor is defective.
Corrective Action	1) Set rack(s) and press [Sampler], then [Start] key to start analysis. 2) If the error persists, contact your Sysmex service representative.

7. Manual CP Unit Errors

Set Piercer Lid

Phenomena	Piercer lid is open when the Start Switch is pressed.
Probable Cause	Sensor switch to detect closed lid is defective.
Corrective Action	1) Make sure to close the piercer lid. 2) If the error persists, contact your Sysmex service representative.

Set Manual Piercer Cover

Phenomena	Manual CP cover is not installed when the Start Switch is pressed.
Probable Cause	Unit cover detection sensor is defective.
Corrective Action	1) Make sure to install the Manual CP cover. 2) If the error persists, contact your Sysmex service representative.

8. Manometer Unit Errors

RBC Slow To Start
RBC Count Too Long

Phenomena	The ball float in the manometer descends to the Stop Level via Start Level slower than the preset time limit. An analysis error may occur, and the "Check Stored Data" message also appears. The sample being processed is completed, and the system returns to Ready. If the system is set to be stopped by this error, the system will be STAT ready for the sample analysis in manual or capillary mode. If the system is set to continue analysis when this error occurs, the system will process the next sample.
Probable Cause	1) Detector aperture is clogged. 2) Vacuum line is blocked or vacuum is low.
Corrective Action	1) Execute clog removal sequence. Refer to *Chapter 5, Section 7.2: Execute RBC Aperture Clog Removal Sequence*. 2) Check vacuum lines for leaks or obstructions. 3) Check and adjust 250 mmHg vacuum if required. Refer to *Chapter 9, Section 4: Main Unit Adjustment*. 4) Clean vacuum orifice. Refer to *Chapter 5, Section 5.1: Clean Orifice*. 5) If the error persists, contact your Sysmex service representative.

RBC Fast To Start
RBC Count Too Short

Phenomena	The ball float in the manometer descends to the Stop Level via Start Level faster than the preset time limit. An analysis error may occur, and the "Check Stored Data" message also appears. The sample being processed is completed, and the system returns to Ready. If the system is set to be stopped by this error, the system will be STAT ready for the sample analysis in manual or capillary mode. If the system is set to continue analysis when this error occurs, the system will process the next sample.
Probable Cause	1) Air bubbles exist inside the manometer unit. 2) Insufficient sample has entered the transducer chamber. 3) The vacuum is high.
Corrective Action	1) Execute clog removal sequence. Refer to *Chapter 5, Section 7.2: Execute RBC Aperture Clog Removal Sequence*. 2) Check that sample is reaching the RBC transducer chamber. 3) Check and adjust 250 mmHg vacuum if required. Refer to *Chapter 9, Section 4: Main Unit Adjustment*. 4) If the error persists, contact your Sysmex service representative.

Close RBC Detector Cover
Close WBC Detector Cover

Phenomena	RBC and/or WBC detector cover is open. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	1) The cover is open. 2) The detector cover sensor is defective.
Corrective Action	1) Close the detector cover(s). 2) If the error persists, contact your Sysmex service representative.

Laser Power Error

Phenomena	The laser output level is outside of the control level. An analysis error may occur, and the "Check Stored Data" message also appears. Analysis cannot be continued until the error is resolved.
Probable Cause	Laser unit is aged.
Corrective Action	1) Check the laser output operation using laser test program. (Refer to *Section 3.12: Test Laser Unit* in this chapter.) 2) Replacement of laser unit is necessary. Contact your Sysmex service representative.

9. Analysis Errors

< Data Error >

Phenomena	Any parameter(s) of the analysis result exceeded the Sampler Stop Limit. If the system is set to be stopped by Stop Limit Error, the system will be STAT ready for the sample analysis in manual or capillary mode. If the system is set to continue analysis when this error occurs, the system will process the next sample.
Corrective Action	1) Check the Stored Data for the sample indicated with a flag "+" or "–" in red back-light. 2) Resume the sampler operation by pressing [Sampler], then [Start] key on the LCD.

< Analysis Error >

Phenomena	An instrument abnormality was detected. A window containing analysis error message(s) appears.
Corrective Action	1) Check the Stored Data for the sample indicated with "Func." or "Result" in ERROR column in the stored data list display (P1). 2) Reset the rack. Press the [Sampler] keypad on the LCD and set manually the Rack No. and the Tube Pos. No. for the next sample. Press [Sampler], then [Start] key to resume the sampler operation.

Background Error

Phenomena	As a result of the background check, any of the following parameters exceeds the acceptable limit: WBC/BASO ≤ 0.10 x $10^3/\mu L$ DIFF ≤ 0.10 x $10^3/\mu L$ RBC ≤ 0.02 x $10^6/\mu L$ HGB ≤ 0.1 g/dL PLT ≤ 10 x $10^3/\mu L$ The background error message window appears with the parameter name as "WBC/BASO Background Error", etc. The system returns to Ready, however, the error message remains on the LCD until the error is resolved.
Probable Cause	1) Transducer aperture is dirty. 2) SRV is dirty. 3) Air bubbles exist in the reagent line tubing. 4) Reagent is contaminated or expired.
Corrective Action	1) Execute clog removal sequence. Refer to *Chapter 5, Section 6.2: Execute RBC Aperture Clog Removal Sequence*. 2) Clean the SRV. Refer to *Chapter 5, Section 5.3: Clean SRV*. 3) Execute a background check by pressing [Auto Rinse] key in the root menu. 4) Replace the reagent. Refer to *Chapter 5, Section 8.1: Replace Reagent*.

PLT Sampling Error
RBC Sampling Error

Phenomena	The ratio of the difference between the maximum and minimum RBC or PLT sampling data to the actual count exceeds a preset value. An analysis error occurs, and the "Check Stored Data" message also appears. When the sample being processed is completed, the system returns to Ready.
Probable Cause	1) RBC detector aperture is dirty. 2) External noise interference is present. 3) A sample abnormality is present.
Corrective Action	1) Check that interfering devices (radio, television receiver, centrifuge or temperature controlled water bath, etc.) are not placed near the instrument. 2) Execute clog removal sequence. Refer to *Chapter 5, Section 7.2: Execute RBC Aperture Clog Removal Sequence*. 3) Reanalyze the sample, if required. 4) If the error persists, clean the RBC transducer and aperture. Refer to *Chapter 5, Section 7.3: Execute Clean RBC Transducer Sequence*, and to *Chapter 5, Section 7.4: Clean RBC Detector Aperture*. 5) If the error still persists, contact the Sysmex service representative.

DIFF Sampling Error
WBC/BASO Sampling Error

Phenomena	The ratio of the difference between the maximum and minimum WBC/BASO or DIFF sampling data to the actual count exceeds a preset value. An analysis error occurs, and the "Check Stored Data" message also appears. When the sample being processed is completed, the system returns to Ready.
Probable Cause	1) WBC flow cell is dirty. 2) Insufficient sample has entered in the WBC mixing chamber. 3) The sheath flow is insufficient. 4) The lysing reagent is insufficient. 5) Sample mixing in the mixing chamber is insufficient. 6) A sheath injector piston malfunction such as a leak 7) The tubing is pinched at the SRV. 8) A sample abnormality is present.
Corrective Action	1) Execute WBC detector cleaning sequence. Refer to *Chapter 5, Section 4.2: Clean WBC Detector.* 2) Reanalyze the sample, if required. 3) If the error persists, contact the Sysmex service representative.

DIFF CCSD Noise Error
PLT CCSD Noise Error
RBC CCSD Noise Error
WBC/BASO CCSD Noise Error

Phenomena	The number of cells in the CCSD (cumulative cell size distribution) curve shows abnormality. An analysis error may occur, and the "Check Stored Data" also appears. When the sample being processed is completed, the system returns to Ready.
Probable Cause	1) External noise interference is present. 2) PCB is defective.
Corrective Action	1) Move the source of external noise (such as radio, centrifuge, temperature controlled water bath, etc.) well away from the instrument. 2) Reanalyze the sample, if required. 3) If the error persists, contact your Sysmex service representative.

Low Count Error

Phenomena	All of the count results are lower than the preset values, even though sufficient volume is detected by the sensor and no aspiration error is detected. An analysis error may occur, and the "Check Stored Data" also appears. When the sample being processed is completed, the system returns to Ready. If the system is set to be stopped by this error, the system will be STAT ready for the sample analysis in manual or capillary mode. If the system is set to continue analysis when this error occurs, the system will process the next sample.
Probable Cause	1) Piercer needle is blocked. 2) SRV is blocked. 3) Whole blood aspiration line is blocked.
Corrective Action	1) Execute shutdown sequence to clean the WB aspiration line and the piercer needle. Refer to *Chapter 5, Section 3.1: Clean Detector Chamber and Manometer (Shutdown).* When the shutdown sequence is complete and system enters Ready, reanalyze the sample. If the same error persists, aliquot CELLCLEAN (or 5% filtered sodium hypochlorite) into 3 collection tubes and analyze these samples in the auto mode to clean the piercer and the whole blood aspiration line. 2) Clean the SRV. Refer to *Chapter 5, Section 5.3: Clean SRV*.

HGB Error (Blank or Sample)

Phenomena	The HGB A/D converted values are out of acceptable range. An analysis error may occur, and the "Check Stored Data" message also appears. When the sample being processed is completed, the system returns to Ready.
Probable Cause	1) Air bubbles are present in the HGB measurement line. 2) HGB flow cell is dirty.
Corrective Action	1) Execute shutdown sequence to clean the HGB flow cell and the measurement lines. Refer to *Chapter 5, Section 3.1: Clean Detector Chamber and Manometer (Shutdown).* 2) Perform a background check by pressing [Auto Rinse] keypad in the root menu. 3) If the error persists, contact Sysmex service representative.

HGB Drain Error

Phenomena	The HGB flow cell cannot be drained completely or drained slowly. An analysis error may occur, and the "Check Stored Data" message also appears. When the sample being processed is completed, the system returns to Ready.
Probable Cause	1) HGB flow cell is blocked. 2) HGB flow cell waste line is bent or blocked.
Corrective Action	1) Check the tubing from the HGB flow cell for bend or clog. 2) Execute shutdown sequence to clean the HGB flow cell and the measurement lines. Refer to *Chapter 5, Section 3.1: Clean Detector Chamber and Manometer (Shutdown).* 3) If the error persists, contact Sysmex service representative.

PDA Error

Phenomena	There is an abnormality in the detecting circuits. A message window appears to indicate the abnormal circuit, as RBC-PDA Error, etc. Analysis cannot be continued until the error is resolved.
Probable Cause	1) External noise interference is present. 2) Cable is disconnected or broken. 3) PCB is defective.
Corrective Action	1) Move the source of external noise (such as radio, centrifuge, temperature controlled water bath, etc.) well away from the instrument. 2) Check the cable connection. 3) Check the PDA function using test program. (Refer to *Section 3.4: Test PDA PCB* in this chapter.) 4) If the error persists after the test program is completed, turn the Main Unit power OFF, then ON again. 5) If the error still persists, contact your Sysmex service representative.

WBC Channel Error

Phenomena	The particles counted by WBC/BASO Channel are differed not less than two times of that by DIFF Channel.
Probable Cause	1) WBC Detector Block is clogged. 2) Air bubbles are aspirated along with a whole blood sample due to a slight short sample. 3) Abnormal sample (such as platelet aggregation, cold protein, deposition etc.)
Corrective Action	1) Execute clean WBC Detector by pressing [Mainte.] key in the root menu and next [Service Sequence] key. (Refer to *Chapter 5, Section 4.2: Execute Clean WBC Detector Sequence*.) 2) Reanalyze the sample, if required. 3) Check the sample by observing smear or counting manually.

10. Subprocessor Errors

Sheath Motor Controller Error
WB Asp Motor Controller Error
Rinse Motor Controller Error

Phenomena	A communication problem exists between the CPU board and the motor(s). An analysis error may occur, and analysis cannot be continued until the error is resolved.
Probable Cause	CPU operation faulty due to sudden noise interference.
Corrective Action	1) Move the source of external noise (such as radio, centrifuge, temperature controlled water bath, etc.) well away from the instrument. 2) Turn the Main Unit power OFF, then ON again. 3) If the error persists, contact Sysmex service representative.

Sampler Com. Error
ID Unit Com. Error

Phenomena	A communication problem exists between the CPU board and the sampler or ID reader. An analysis error may occur, and analysis cannot be continued until the error is resolved.
Probable Cause	1) CPU operation faulty due to sudden noise interference. 2) The ID reader or sampler is disconnected or improperly connected.
Corrective Action	1) Move the source of external noise (such as radio, centrifuge, temperature controlled water bath, etc.) well away from the instrument. 2) Verify the cable between the Main Unit and the Sampler/ID reader is securely connected. 3) Turn the Main Unit power OFF, then ON again. 4) Check the ID reader function using test program. Refer to *Section 3.7: Test Bar Code Reader* in this chapter. 5) If the error persists, contact Sysmex service representative.

11. Memory Errors

BBM Unstorageable

Phenomena	Indicates the stored data exceeds 1000 samples.
Probable Cause	Number of samples stored has exceeded 1000.
Corrective Action	1) Delete the stored data. Refer to *Chapter 4, Section 12: Delete Stored Data* until the number of stored data becomes less than 1000. 2) Set the Auto Erase mode setting to "FIFO". Refer to *Chapter 11, Section 2.3: Auto Erase*.

Check Sum Error

Phenomena	The analysis data or the setting values are not stored correctly.
Probable Cause	1) The lithium battery is weak or dead. 2) Defective PCB.
Corrective Action	1) Check the Stored Data using test program. Refer to *Section 3.8: Test Memory* in this chapter. 2) If any item results in NG, contact Sysmex service representative. 3) Turn the Main Unit power OFF. Verify that the battery is connected correctly (see *Appendix B: Installation*). Wait a few minutes, and then turn the power ON. 4) Reanalyze the last sample, if necessary. 5) If the error persists, contact Sysmex service representative.

Control Table Error

Phenomena	The control table for the stored data has some abnormalities.
Probable Cause	1) The lithium battery is weak or dead. 2) Defective PCB
Corrective Action	1) Output all stored data, if possible. 2) Erase all stored data using "Stored Data" - "Delete" - "All" program. 3) Turn the Main Unit power OFF. Verify that the battery is connected correctly (see *Appendix B: Installation*). Wait a few minutes, and then turn the power ON. 4) Reanalyze the last sample, if necessary. 5) If the error persists, contact Sysmex service representative.

Program Version Error

Phenomena	A program version is incorrectly set. Analysis cannot continue until the error is resolved.
Probable Cause	1) Program version is incorrectly set. 2) CPU operation faulty due to sudden noise interference
Corrective Action	1) Check and set the program version using version check program. Refer to *Section 3.13: Version Check* in this chapter. 2) Turn OFF, then ON the Main Unit power. 3) If the error persists after power ON, contact Sysmex service representative.

RAM Error

Phenomena	A data problem exists in RAM (random access memory). Analysis cannot continue until the error is resolved.
Probable Cause	CPU operation faulty due to sudden noise interference
Corrective Action	1) Move the source of external noise (such as radio, centrifuge, temperature controlled water bath, etc.) well away from the instrument. 2) Turn the Main Unit power OFF, then ON again. 3) If the error persists, contact Sysmex service representative.

Seq. No. Overflow

Phenomena	Indicates the analysis sequence number exceeds 65 000.
Probable Cause	The analysis sequence number exceeds 65 000.
Corrective Action	1) Turn the Main Unit power OFF, then ON again. The sequential number will be reset to 1. 2) Reanalyze the last sample, if necessary. 3) If the error persists, contact Sysmex service representative.

Stored Data Error

Phenomena	A data problem exists in the data stored in the hard disk memory or BBURAM. Analysis cannot continue until the error is resolved.
Probable Cause	CPU operation faulty due to sudden noise interference
Corrective Action	1) Move the source of external noise (such as radio, centrifuge, temperature controlled water bath, etc.) well away from the instrument. 2) Check the Stored Data using test program. Refer to *Section 3.8: Test Memory* in this chapter. 3) If the error persists after the test program is completed, turn the Main Unit power OFF, then ON again. 4) If the error still persists, contact Sysmex service representative.

Stored Data Full

Phenomena	Number of samples stored has exceeded memory capacity. Analysis cannot continue until the error is resolved.
Probable Cause	Number of samples stored has exceeded 1000.
Corrective Action	1) Delete the stored data. Refer to *Chapter 4, Section 12: Delete Stored Data* until the number of stored data becomes less than 1000. 2) Set the Auto Erase mode setting to "FIFO". Refer to *Chapter 11, Section 2.3: Auto Erase*.

12. ID Errors

ID Read Error
Rack ID Read Error

Phenomena	ID reader cannot read the ID bar code label correctly attached on a collection tube or a sample rack. When the sample being processed is completed, the system returns to Ready. If the system is set to be stopped by this error, the system will be STAT ready for the sample analysis in manual or capillary mode. If the system is set to continue analysis when this error occurs, the system will process the next sample.
Probable Cause	1) The ID bar code label is stained with blood or is dirty. 2) The position of ID bar code label is incorrect. 3) The ID bar code label is out of specification.
Corrective Action	1) Check that the ID bar code label is clear and smooth and is attached to the tube or rack correctly. Refer to *Appendix C: Technical Information* for the ID bar code label specification. 2) Correct the sample ID number, if necessary. 3) Reset the rack and press [Sampler], then [Start] key to start analysis. 4) If the error persists, contact Sysmex service representative.

13. Host Errors

ACK Code Error

Phenomena	The system has failed to establish communication with the host computer after three attempts.
Probable Cause	The HC setting is not correct.
Corrective Action	1) Check the HC settings. Refer to *Chapter 11, Section 5.1: HC Setting*. 2) If the error persists, contact Sysmex service representative.

ACK Time Out Error

Phenomena	Indicates that the ACK signal cannot be received from the host computer during a specified time period after the data has been transferred. (Only when Class B protocol is selected.
Probable Cause	1) The HC setting is not correct. 2) The host computer has a problem or is down (not functioning). 3) The interface cable is disconnected or improperly connected.
Corrective Action	1) Check the HC settings. Refer to *Chapter 11, Section 5.1: HC Setting*. 2) Check the HC status in the Status Display by pressing [Status] key in the root menu. 3) Check that the interface cable is securely connected. 4) If the error persists, contact Sysmex service representative.

HC Communication Error

Phenomena	A communication problem exists between the Main Unit and the host computer.
Probable Cause	1) The power of the host computer is OFF. 2) The host computer is disconnected or improperly connected. 3) The host computer is not ready for data transmission.
Corrective Action	1) Check the host computer power and the system status. 2) Verify the cable between the Main Unit and the host computer is securely connected. 3) Set the host computer connection to "Not Connected", then reset to "Connected". Refer to *Chapter 11, Section 5.1: HC Setting*. 4) If the error persists, contact Sysmex service representative.

Not Assigned

Phenomena	The output to HC is assigned when the host computer is not specified for connection. Output to HC is impossible until the error is resolved.
Probable Cause	HC has not been specified in Settings program.
Corrective Action	1) Set the HC to "Connected". Refer to *Chapter 11, Section 5.1: HC Setting* for the procedures. 2) If the error persists, contact Sysmex service representative.

Not Transmissible

Phenomena	The output data is not received by the host computer.
Probable Cause	1) The HC setting is not correct. 2) The HC has a problem or is down (not functioning). 3) The interface cable is disconnected or improperly connected.
Corrective Action	1) Check the HC settings. Refer to *Chapter 11, Section 5.1: HC Setting*. 2) Check the HC status in the Status Display by pressing [Status] key in the root menu. 3) Check that the interface cable is securely connected. 4) If the error persists, contact Sysmex service representative.

Off Line

Phenomena	The output to HC is assigned when the DSR signal from the host computer is OFF. Output to HC is impossible until the error is resolved.
Probable Cause	1) The host computer power is OFF. 2) The HC is in the off line condition. 3) The interface cable is disconnected or improperly connected.
Corrective Action	1) Check that the host computer is powered ON and is on-line. 2) Check that the interface cable is securely connected. 3) If the error persists, contact Sysmex service representative.

14. Printer Errors

GP Not Ready

Phenomena	The output to GP is not accepted. Output to GP is impossible until the error is resolved.
Probable Cause	1) The printer is out of paper. 2) GP printer power is OFF or is off-line. 3) The interface cable is disconnected or improperly connected. 4) A printer malfunction such as a paper jam occurred. 5) Defective PCB
Corrective Action	1) Supply the paper. 2) Check the printer power is ON. 2) Verify the cable between the Main Unit and the printer is securely connected. 3) Set the GP status to "Connected". Refer to *Chapter 11, Section 5.2: GP Setting*. 4) If the error persists, contact Sysmex service representative.

GP Off Line

Phenomena	The output to GP is assigned when the printer is in the off line condition or when a printer error occurs. Output to GP is impossible until the error is resolved.
Probable Cause	1) The printer is in the off line condition. 2) GP printer power is OFF. 3) A printer hardware error occurred.
Corrective Action	1) Check the printer power is ON. 2) Verify the cable between the Main Unit and the printer is securely connected. 3) Set the GP status to "Connected". Refer to *Chapter 11, Section 5.2: GP Setting*. 4) If the error persists, contact Sysmex service representative.

Not Assigned

Phenomena	The output to GP or DP is assigned when the printer is not specified for connection. Output to GP or DP is impossible until the error is resolved.
Probable Cause	GP or DP has not been specified in Settings program.
Corrective Action	1) Set the GP or DP to "Connected". Refer to *Chapter 11, Section 5.2: GP Setting* or *Section 5.3: DP Setting* for the procedures. 2) If the error persists, contact Sysmex service representative.

Off Line/Device Error

Phenomena	The output to GP or DP is assigned when the printer is in the off line condition or when a printer error occurs. Output to GP or DP is impossible until the error is resolved.
Probable Cause	1) GP or DP printer power is OFF or is off-line. 2) A printer hardware error occurred.
Corrective Action	1) Check the printer power is ON. 2) Set the printer in the on line condition. 3) If the error persists, contact Sysmex service representative.

NOTE: "GP Off Line" error message will disappear automatically when the printer becomes on-line condition. However the beep sound will not stop until [Alarm Reset] key is pressed.

Paper Empty

Phenomena	The paper for the printer has run out. Output to the printer is impossible until the error is resolved.
Probable Cause	The printer is out of paper.
Corrective Action	Supply the printer paper.

Power/Cable OFF

Phenomena	The printer is powered OFF or the interface cable is disconnected. The print out to GP or DP cannot be performed.
Probable Cause	1) The printer is not powered ON. 2) The interface cable is disconnected.
Corrective Action	1) Power ON the printer. 2) Verify that the interface cable is securely connected. 3) If the error persists, contact Sysmex service representative.

15. QC Errors

< $\overline{X}$ M Limit Error >
< L-J Limit Error >
< $\overline{X}$ Limit Error >

Phenomena	An error is detected in the QC ($\overline{X}$ M, $\overline{X}$ or L-J). The "Check Control Chart" or "Reanalyze Sample" message will also appear. (Refer to *Chapter 6* for QC error messages.) When the sample being processed is completed, the system returns to Ready. If the system is set to be stopped by this error, the system will be STAT ready for the sample analysis in manual mode. If the system is set to continue analysis when this error occurs, the system will process the next sample.
Probable Cause	1) The QC data exceeds the control limits. 2) The analyzed sample or batch has abnormality. 3) Control blood has abnormality.
Corrective Action	1) Check the error on the control chart and reanalyze the control material, if needed. Refer to *Chapter 6: Quality Control*. 2) Check the control sample or SF CHECK for any signs of abnormality. 3) Calibrate the instrument, if required. Refer to *Chapter 7: Calibration*. 4) If the error persists, contact Sysmex service representative.

< Control Expired >

Phenomena	Control blood which has been expired is analyzed. When the sample being processed is completed, the system returns to Ready.
Probable Cause	1) Control blood is expired. 2) The expiration of the Control blood is not registered for the QC File.
Corrective Action	1) Check the QC File Information. Refer to *Chapter 6: Section 6.6: Lot Information.* 2) Analyze a new vial of control blood which has not expired. 3) If the error persists, contact Sysmex service representative.

< QC Analysis Error >

Phenomena	An instrument abnormality was detected during QC analysis. A window containing analysis error message(s) appears.
Corrective Action	1) Check the Stored Data for the QC sample indicated with "Func." or "Result" in ERROR column in the stored data list display (P1). 2) Reset the rack. Press the [Sampler] keypad on the LCD and set manually the Rack No. and the Tube Pos. No. for the next sample. Press [Sampler], then [Start] key to resume the sampler operation. 3) If the error persists, contact Sysmex service representative.

16. Maintenance Instruction Messages

When the counters for each unit reach the cycle count needing cleaning or replacement, an instruction message will be displayed at the system power ON .

Clean the Orifice

Probable Cause	Vacuum Orifice counter has reached 2500 or 1 month passed after the previous maintenance of Orifice.
Corrective Action	1) Clean the Orifice. Refer to *Chapter 5, Section 5.1: Clean Orifice*. 2) Reset the Vacuum Orifice counter. Refer to *Chapter 5, Section 9: Reset the Counter.*

Clean the SRV

Probable Cause	SRV counter has reached 2500 or 1 month passed after the previous maintenance of SRV.
Corrective Action	1) Clean the SRV. Refer to *Chapter 5, Section 5.3: Clean SRV*. 2) Reset the SRV counter. Refer to *Chapter 5, Section 9: Reset the Counter.*

Clean the Waste Chamber

Probable Cause	Waste Chamber counter has reached 2500 or 1 month passed after the previous maintenance of Waste Chamber.
Corrective Action	1) Clean the Waste Chamber. Refer to *Chapter 5, Section 5.2: Execute Clean Waste Chamber Sequence*. 2) Reset the Waste Chamber counter. Refer to *Chapter 5, Section 9: Reset the Counter.*

Clean the WBC Detector

Probable Cause	WBC Detector counter has reached 600 or 1 week passed after the previous maintenance of WBC Detector.
Corrective Action	1) Clean the WBC Detector. Refer to *Chapter 5, Section 4.2: Clean WBC Detector*. 2) Reset the WBC Detector counter. Refer to *Chapter 5, Section 9: Reset the Counter.*

Replace Piercer

Probable Cause	Piercer counter has reached 30 000.
Corrective Action	1) Replace the piercer. Refer to *Chapter 5, Section 8.2: Replace the Piercer*. 2) Reset the Piercer counter. Refer to *Chapter 5, Section 9: Reset the Counter.*

3. TEST PROGRAMS

The SF-3000 is equipped with test programs for checking system operation and finding the causes of abnormalities detected in the SF-3000 system.

3.1 Executing a Test Program

(1) Press [Mainte.] keypad in the root menu. The Maintenance second menu will be displayed.

NOTE: If the [Mainte.] keypad is not displayed on the LCD, press [More] key to alter the displayed root menu.

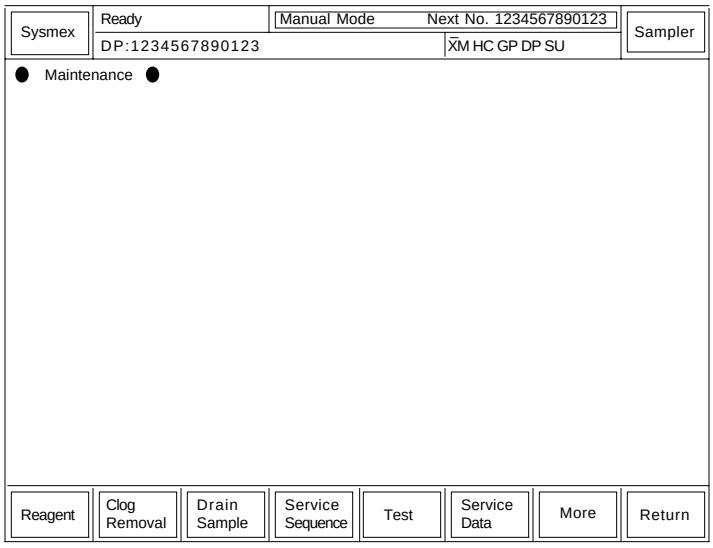


Figure 8-5: Maintenance Second Menu Screen

(2) Select [Test] from the maintenance second menu. The Test screen shown below will appear.

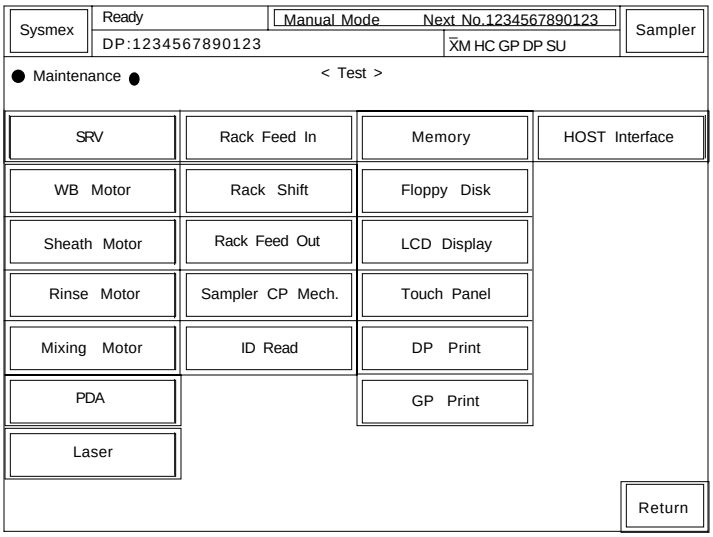


Figure 8-6: Test Screen

(3) Press a desired keypad to execute the test program. The test execution message will appear.

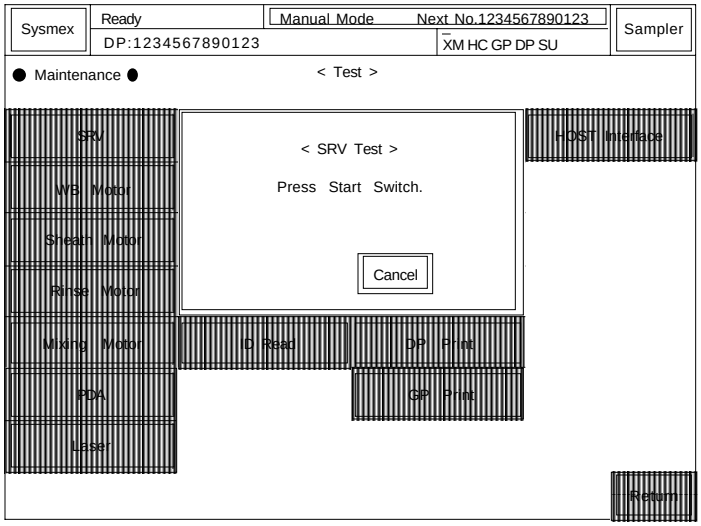


Figure 8-7: Test Execution Message Window

(4) Refer to the following sections for the procedures.

NOTE:	The test programs can only be run when the system is in the Ready mode. If you attempt to run these programs during analysis, a "Wait until Ready" message will appear, and the programs will not be executed. Also note that analysis is not possible while test programs are in the progress.

3.2 Test SRV

This program performs test operation of the SRV (Sample Rotor Valve) and positions the valve in the correct initial position.
Run this test if an "SRV Initial Position Error" or "SRV Move Position Error" occurs and analysis cannot be performed. If the test corrects the error, analysis will be possible after the system enters the Ready mode.

(1) Open the front cover and set the stop bar in place.

> **WARNING!** When working with the front cover open, make sure that the stop bar is in place to avoid accidental closure.

(2) Bring the Test screen by pressing [Mainte.] and then [Test] keypads.

(3) Press the [SRV] keypad from the Test screen. The message "Press Start Switch" will appear.

(4) Press the Start Switch. SRV operation will begin. Check SRV operation using the figure below as a guide. When operation ends, the valve will return to the initial position.

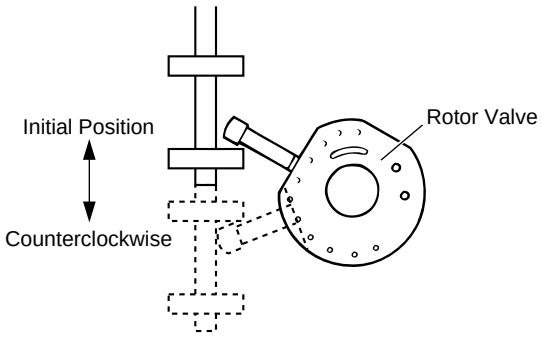


Figure 8-8: Sample Rotor Valve Operation

(5) Press [Return] to end the test program.
The system automatically performs auto rinse to clean the hydraulic lines.

3.3 Test Motor

Following 4 programs are provided for the motor operation test.

- WB Asp Motor
- Sheath Motor
- Rinse Motor
- Mixing Motor

1. WB Asp (Whole Blood Aspiration) Motor

This program performs test operation of the Whole Blood Aspiration Motor and positions the motor in the correct initial position.
Run this test if a "WB Asp Motor Function Error" occurs and analysis cannot be performed. If the test corrects the error, analysis will be possible after the system enters the Ready mode.

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads.

(2) Press the [WB Motor] keypad from the Test screen. The message "Press Start Switch" will appear.

(3) Press the Start Switch. WB Aspiration Motor operation will begin. The WB Aspiration Pump moves as shown in figure below.
During test operation, the message "Executing WB Motor test. Please wait." is displayed.

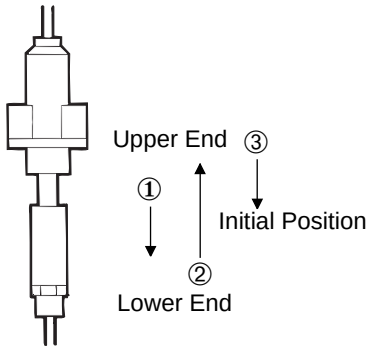


Figure 8-9: WB Aspiration Pump Operation

NOTE:	Only when it is required by Sysmex service representative, open the Main Unit front panel behind the Sampler Unit (if installed), and observe the operation of Whole Blood Aspiration Pump with his/her assistance.

CAUTION:	DO NOT open the front panel or try to remove the Sampler Unit without instruction and assistance of Sysmex service representative.

WARNING! The hydraulic system in the instrument should be considered potentially biohazardous. Do not handle the tubing, chambers, connectors, etc. without proper protective equipment. Wear rubber gloves when servicing is required and wash your hands with an antiseptic solution after completing the procedure.

(4) When operation ends, the message disappears. The WB pump will return to the initial position.

(5) Press [Return] to end the test program.
The system automatically performs auto rinse to clean the hydraulic lines.

2. Sheath Injector Motor

This program performs test operation of the Sheath Injector Piston Motor and positions the motor in the correct initial position. Run this test if a "Sheath Motor Function Error" occurs and analysis cannot be performed. If the test corrects the error, analysis will be possible after the system enters the Ready mode.

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [Sheath Motor] keypad from the Test screen. The message "Press Start Switch" will appear.

(3) Press the Start Switch. Sheath motor operation will begin. The Sheath Injector Piston moves as displayed in the figure below.
During test operation, the message "Executing Sheath Motor test. Please wait." is displayed.

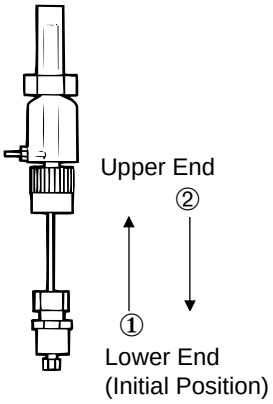


Figure 8-10: Sheath Injector Piston Operation

NOTE:	Only when it is required by Sysmex service representative, open the Main Unit left side cover and observe the operation of Sheath Injector Piston with his/her assistance.

CAUTION:	DO NOT open the left side cover without instruction and assistance of Sysmex service representative to observe Sheath Injector Piston operation.

WARNING! The hydraulic system in the instrument should be considered potentially biohazardous. Do not handle the tubing, chambers, connectors, etc. without proper protective equipment. Wear rubber gloves when servicing is required and wash your hands with an antiseptic solution after completing the procedure.

(4) When operation ends, the message disappears. The piston will return to the initial position.

(5) Press [Return] to end the test program.
The system automatically performs auto rinse to clean the hydraulic lines.

3. Rinse Mechanism Motor

This program performs test operation of the Manual Rinse Mechanism Motor and positions the mechanism in the correct initial position.
Run this test if an "Rinse Motor Function Error" occurs and analysis cannot be performed. If the test corrects the error, analysis will be possible after the system enters the Ready mode.

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [Rinse Motor] keypad from the Test screen. The message "Press Start Switch" will appear.

(3) Press the Start Switch. Rinse Mechanism motor operation will begin. Check motor operation by observing Manual Rinse Mechanism as displayed in figure below.
During test operation, the message "Executing Rinse Motor test. Please wait." is displayed.

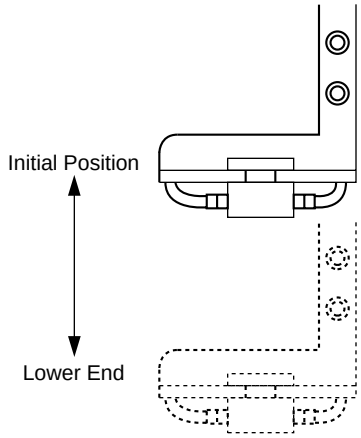


Figure 8-11: Manual Rinse Mechanism Operation

(4) When operation ends, the message disappears. The mechanism will return to the initial position.

(5) Press [Return] to end the test program.
The system automatically performs auto rinse to clean the hydraulic lines.

4. Reaction Chamber Mixing Motor

This program performs test operation of the Reaction Chamber Mixing Motor and displays the rotation speed of the motor. Run this test if a "Mixing Motor Speed Error" occurs and analysis cannot be performed. If the test corrects the error, analysis will be possible after the system enters the Ready mode.

(1) Open the front cover and set the stop bar in place.

WARNING! When working with the front cover open, make sure that the stop bar is in place to avoid accidental closure.

(2) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(3) Press the [Mixing Motor] keypad from the Test screen. The message "Press Start Switch" will appear.

(4) Press the Start Switch. Mixing motor operation will begin and the rotation speed will be displayed and updated every 2.4 seconds. Check if the rotation speed is stable within the normal range of 1600 - 2000 rpm.

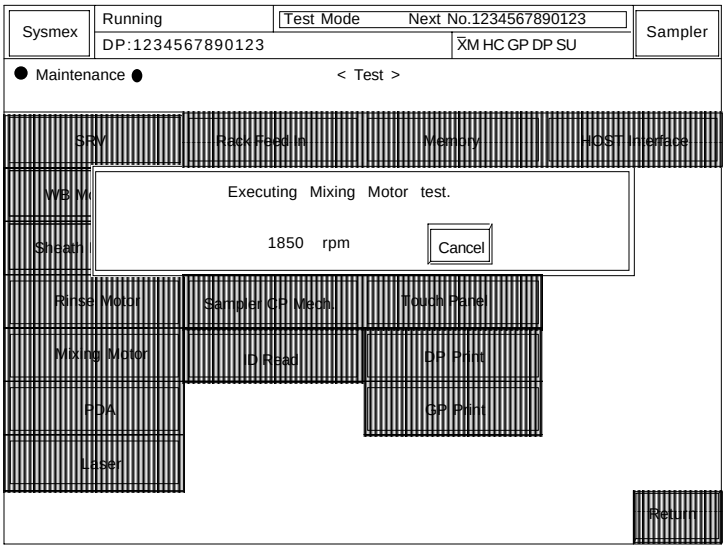


Figure 8-12: Mixing Motor Operation Speed

(5) Press [Cancel] to end the Mixing Motor test program.

(6) Press [Return] to end the Test program.

3.4 Test PDA PCB

Use this program to test whether the PDA circuit boards are operating correctly.

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [PDA] keypad from the Test screen. The message "Press Start Switch" will appear.

(3) Press the Start Switch. The PDA board check will begin. The test will complete in approx. 10 seconds.

The "PDA Error" message appears in the system status area if there is abnormality in the PDA circuits. Stop the alarm by pressing [Alarm Reset] key and contact your Sysmex service representative.

(4) Press [Return] to end the test program. The Maintenance second menu appears.

(5) Press [Return] to exit the Maintenance program. The PDA test result is displayed in the graphic screen. The test result is indicated in the ID No. area.
"PDA-CHK-OK" signifies that the PDA circuits are normal.
"PDA-CHK-NG" signifies that there is abnormality in the PDA analysis circuits.

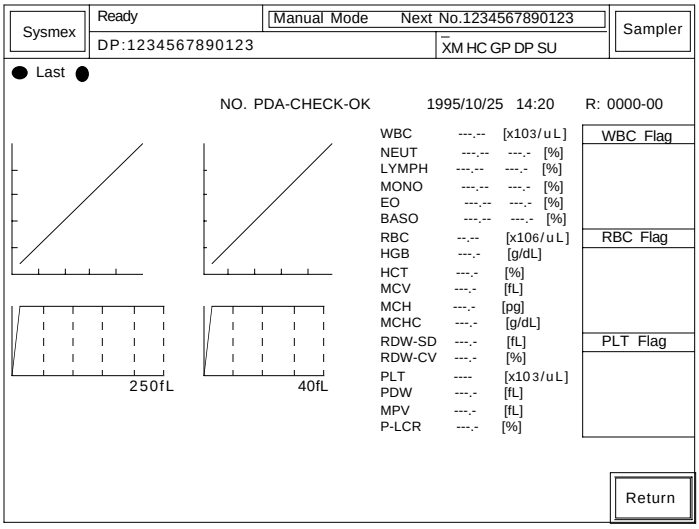


Figure 8-13: PDA Check Screen

3.5 Test Laser Unit

This program tests the laser unit output function. Run this test if a "Laser Power Error" occurs and analysis cannot be performed. If the test corrects the error, analysis will be possible after the system enters the Ready mode.

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

NOTE:	If the [Mainte.] keypad is not displayed on the LCD, press [More] key to change the displayed root menu.

(2) Press the [Laser] keypad from the Test screen. The message "Press Start Switch" will appear.

(3) Press the Start Switch. The laser output begins.
During the test operation, the message "Executing Laser test. Please wait." is displayed.

(4) When the Laser Test completes without any abnormality detected, the system returns to Ready status. Press [Return] to end the test program.

3.6 Test Sampler

Following 4 programs are provided for the sampler operation test.

- Rack Feed In
- Rack Feed Out
- Rack Shift
- Sampler CP Mech.

1. Rack Feed In

Select this program to execute the Rack Feed In operation test.

(1) Set the rack in place on the right rack pool.

(2) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(3) Press the [Rack Feed In] keypad from the Test screen. The message "Set Rack and Press Start Switch" will appear.

(4) Press the Start Switch. Rack feed in operation will begin. Check the sampler operation.

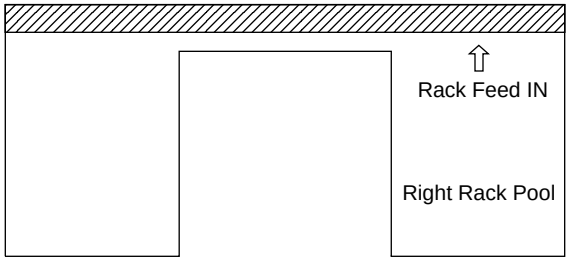


Figure 8-14: Rack Feed In Operation

(5) Press [Return] to end the test program.

2. Rack Shift

Select this program to execute the Rack Shift operation test.

(1) Set the rack in place in the extreme right of the sampler analysis line.

(2) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(3) Press the [Rack Shift] keypad from the Test screen. The message "Set Rack and Press Start Switch" will appear.

(4) Press the Start Switch. Rack shift operation will begin. Check the sampler operation.

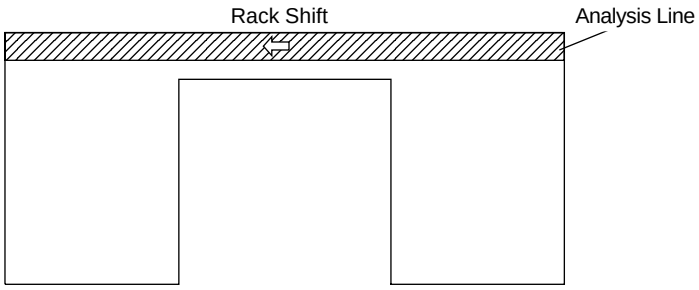


Figure 8-15: Rack Shift Operation

(5) Press [Return] to end the test program.

3. Rack Feed Out

Select this program to execute the Rack Feed Out operation test.

(1) Set the rack in place in the extreme left of the sampler analysis line.

(2) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(3) Press the [Rack Feed Out] keypad from the Test screen. The message "Set Rack and Press Start Switch" will appear.

(4) Press the Start Switch. Rack feed out operation will begin. Check the sampler operation.

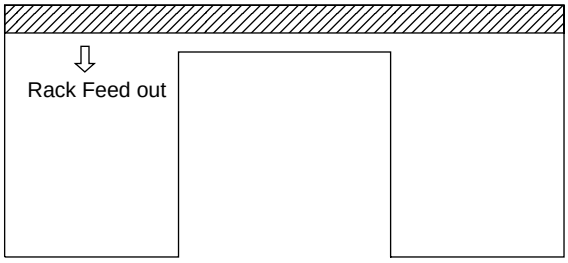


Figure 8-16: Rack Feed Out Operation

(5) Press [Return] to end the test program.

4. Sampler CP Mech.

Select this program to execute test operation of the mixing and aspiration mechanism in the Auto Closed Sampler. Execute this test when one of the following error messages appears and sample analysis cannot be performed. If the test corrects the error, sampler analysis can be performed.

"Tube Invert Position Error"	"Hand Initial Position Error"
"Hand Move Position Error"	"Hand Upper Position Error"
"Hand Lower Position Error"	"Set Piercer Cover"

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [Sampler CP Mech.] keypad from the Test screen. The message "Press Start Switch" will appear.

(3) Press the Start Switch. The cap piercer and aspiration mechanism operation will be executed, and the hand will return to its initial position. Check the operation using the figure below as a guide.

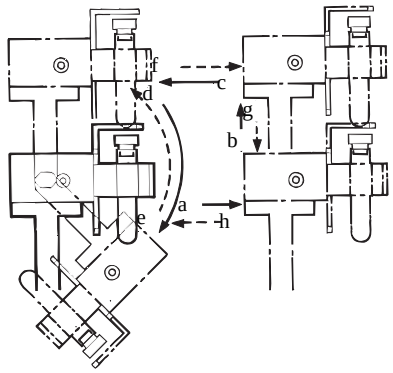


Figure 8-17: CP Mechanism Operation

(4) Press [Return] to end the test program.

3.7 Test Bar Code Reader

Use this program to test the ID Read function.

(1) Place bar-coded tubes in a sampler rack, and place the rack in the right rack pool.

(2) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(3) Press the [ID Read] keypad from the Test screen. The message "Set Rack and Press Start Switch" will appear.

> **NOTE:** If the ID reader is set to "Not Used" in the settings program, the [ID Read] key is masked and cannot be accessed.

(4) Press the Start Switch.
Rack feed in, rack shift, and then ID read operations will be executed, and the Sample No. read will be displayed on the LCD. Verify that the sample No. is read correctly.

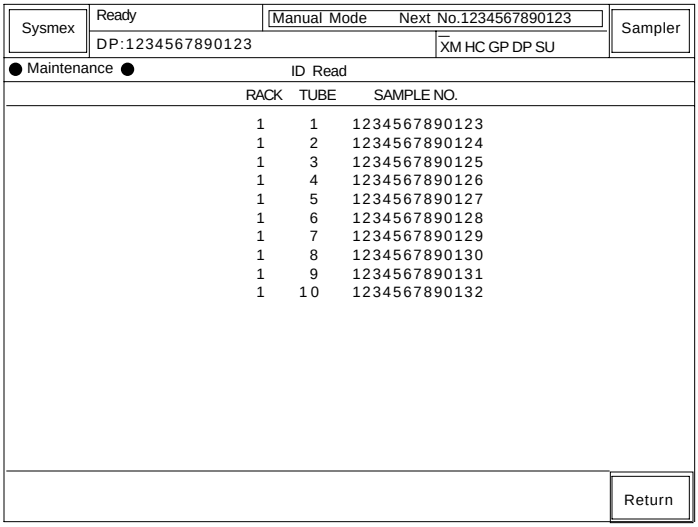


Figure 8-18: ID Read Display

(5) Press [Return] to end the test program.

3.8 Test Memory

This program provides a display of the stored data check window, and shows the test results.

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [Memory] keypad from the Test screen. The stored data check window will appear showing the check results of the Stored Data, Stored Data Table, Setting Data and QC Data.

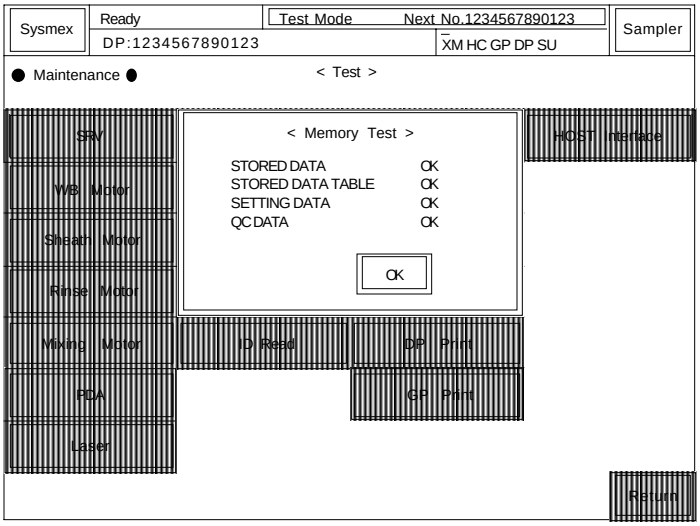


Figure 8-19: Stored Data Check Window

"OK" indicates that data is normal. "NG" indicates that there is an abnormality in the data. If "NG" is displayed, contact your Sysmex service representative.

(3) Press [OK] key to end the Memory Test program.

(4) Press [Return] to end the Test program.

3.9 Test Floppy Disk

Use this program to test writing and reading of data to and from the floppy disk.

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [Floppy Disk] keypad from the Test screen. The message "Insert Floppy Disk." will appear.

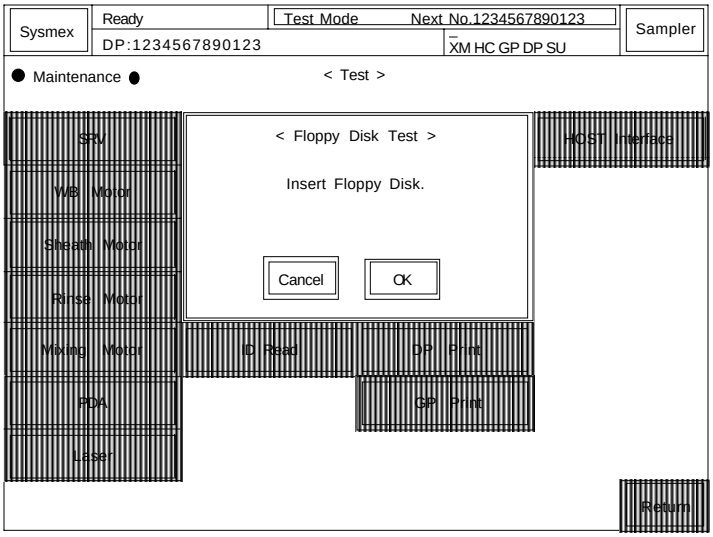


Figure 8-20: Insert FD Window

(3) Insert a pre-formatted floppy disk into the floppy disk drive.

> **NOTE:** A floppy disk can be formatted using "Mainte." - "Format FD" program. Refer to *Chapter 5, Section 10: Format FD*.

(4) If the disk is normal, the display will return to the previous screen.

(5) If the floppy disk is abnormal, an error message will appear.

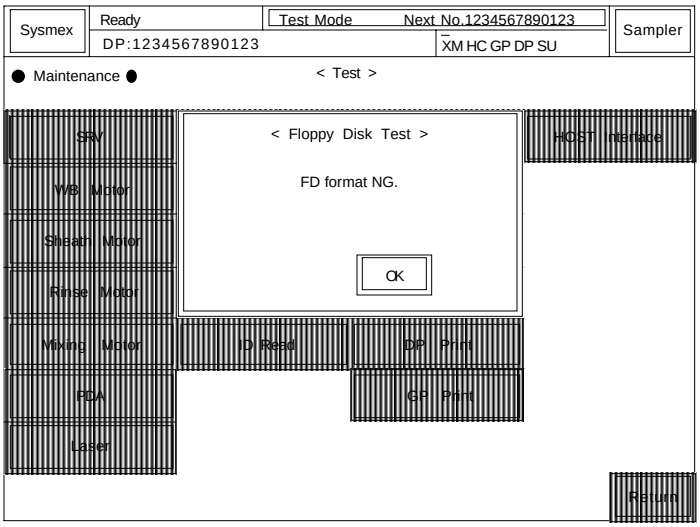


Figure 8-21: When FD Test Error Occurred

NOTE:	A full floppy disk or unformatted floppy disk is assumed as abnormal and the message "FD format NG" will be displayed.

(6) Press [OK] to end the FD Test program.

(7) Press [Return] to end the Test program.

3.10 Test LCD Display

Use this program to check the LCD Display and Control Circuits. This program performs successive tests on the LCD color screen.

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [LCD Display] keypad from the Test screen. The LCD displays one color for 10 seconds and automatically changes the colors in the following order:

(Start) black → red → green → yellow → blue → purple → light blue → white → black → red → green → yellow → blue → purple → light blue → white (end)

> **NOTE:** Pressing any part of the LCD will change the displayed color before 10 seconds.

(3) After the display becomes white the second time, the test program ends automatically and the Test screen will appear.

> **NOTE:** This program cannot be stopped halfway.

(4) Press [Return] to end the Test program.

3.11 Test Touch Panel

Use this program to test whether input from the LCD Touch Panel is being correctly received.

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [Touch Panel] keypad from the Test screen. The touch panel input test screen will appear as shown below.

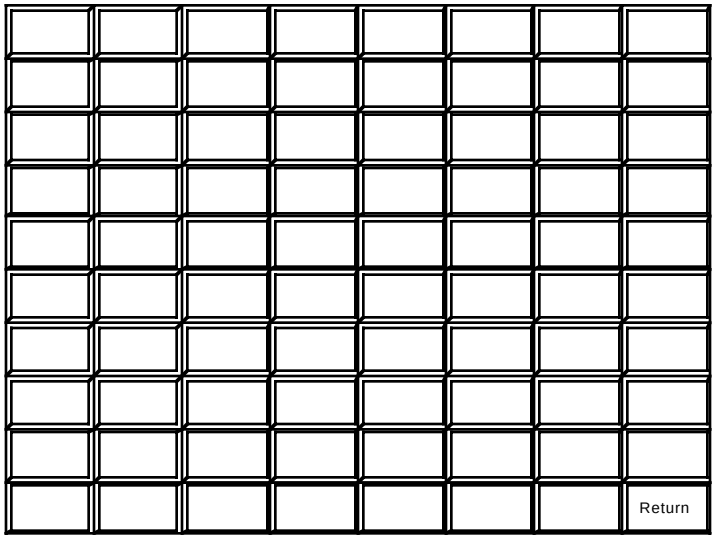


Figure 8-22: Touch Panel Test Screen

(3) Press any keypad to test its input. The pressed keypad will be backlit in light blue.

(4) Press [Return] to end the Touch Panel Test program.

(5) Press [Return] to end the Test program.

3.12 Test Output

Following 3 programs are provided to test the output to the printers and/or host computer.

• DP Print • GP Print • Host Interface

1. DP (Data Printer) Print

Use this program to test the Data Printer. (The data printer is tested using the currently set print format.)

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [DP Print] keypad from the Test screen. The Data Printer will print out a dummy data.

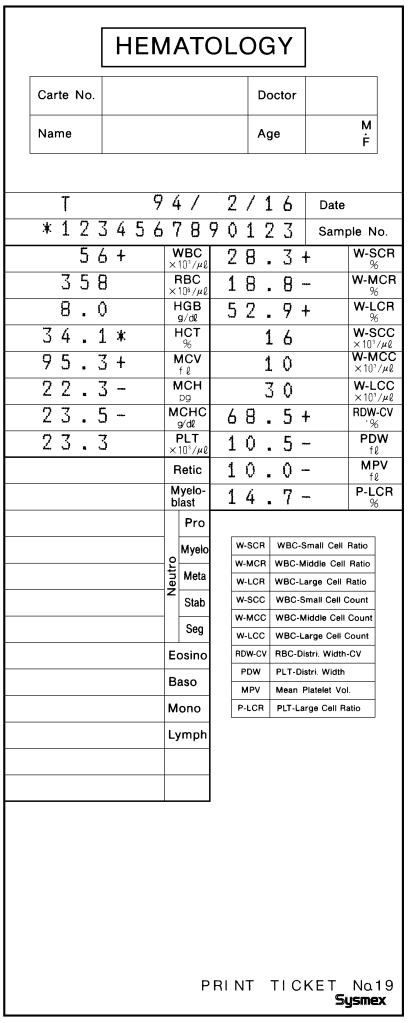


Figure 8-23: DP Test Print Example

2. GP (Graphic Printer) Print

Use this program to test the Graphic Printer or Line Printer. (The printer is tested using the currently set print format.)

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [GP Print] keypad from the Test screen. The Graphic Printer will print out a dummy data.

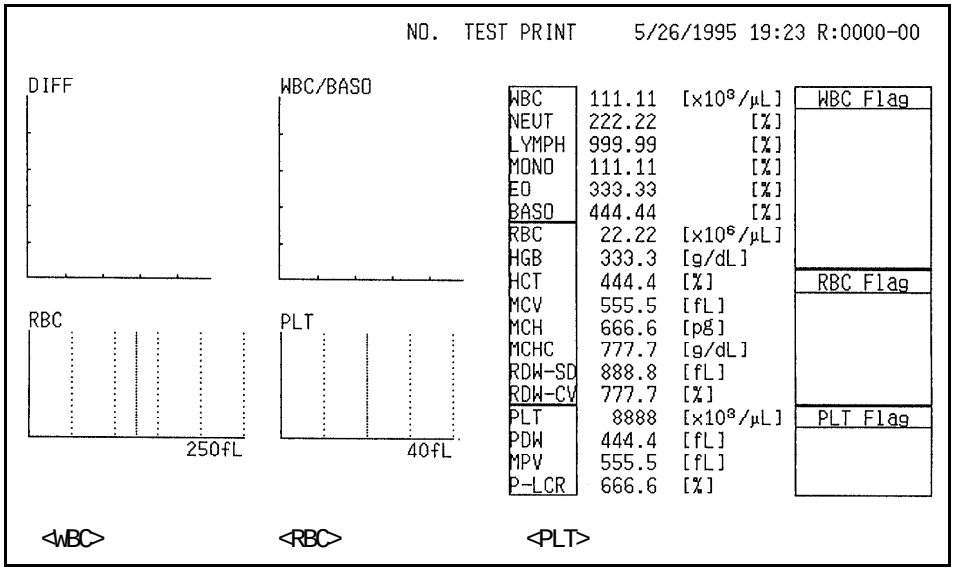


Figure 8-24: GP Test Print Example

NOTE:	Scattergrams are not printed.

3. HC (Host Computer) Output

Use this program to test the interface with the Host Computer by transmitting a dummy data to the Host Computer.

(1) Bring the Test screen by pressing [Mainte.] and then [Test] keypads (Refer to *Section 3.1* in this chapter).

(2) Press the [HOST Interface] keypad from the Test screen. A dummy data will be transmitted to the Host Computer.

```
HC Test Dummy Data (234 bytes including STX and ETX)
  D1U05259500000000000   TEST PRINT00000000000000000
  00111110222203333044440555506666077770888801111022
  22033330444405555099999011111022222033333044444077
  77088880444405555066660000000000000000000000000000
  00000000000000000000000000000000
```

Figure 8-25: Host Computer Output Example

3.13 Version Check

Use this program to check the program versions of the system.
The version check program checks whether programs are correctly read from a floppy disk or PROM. It does this by checking if the registered correct check sum values are the same as the current check sum values.

(1) Press [Mainte.] keypad in the root menu. The Maintenance second menu will be displayed.

NOTE: If the [Mainte.] keypad is not displayed on the LCD, press [More] key to change the displayed root menu.

(2) Select [More] and [Version Check] from the Maintenance second menu.

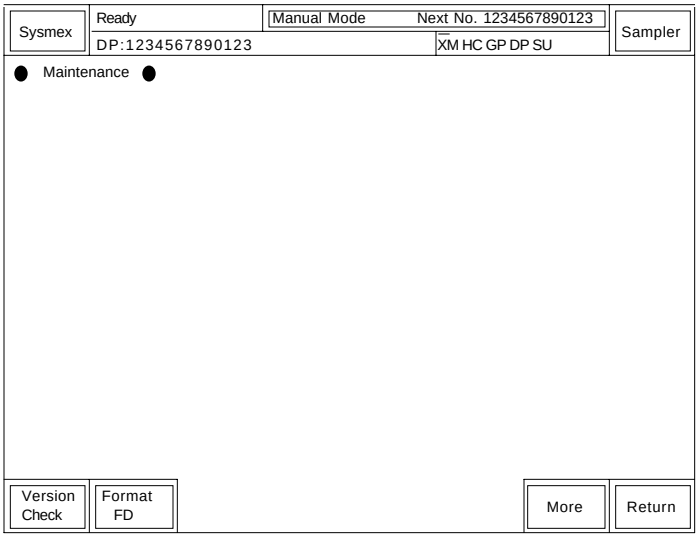


Figure 8-27: Maintenance Second Menu Screen (Altered)

(3) The Version Check screen will appear. All the program versions will be displayed. The system reads and displays the current check sum values.
If the read values match the set values, "Complete" appears on the right of the values.

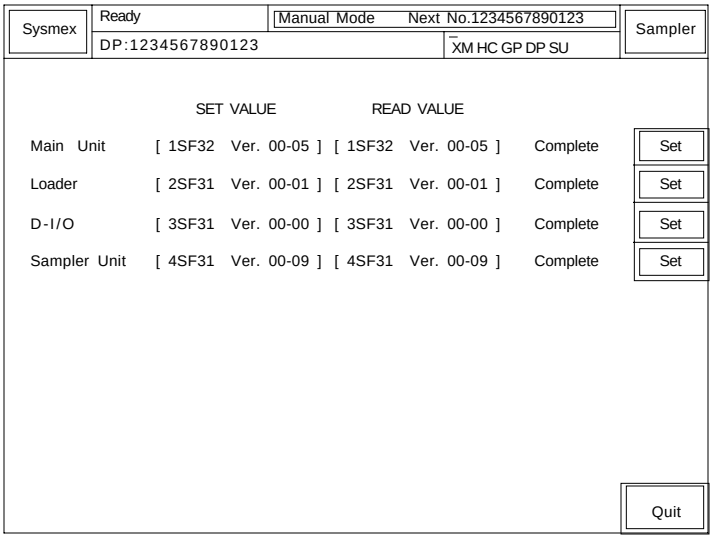

Sysmex
Ready
Manual Mode Next No.1234567890123
DP:1234567890123
XM HC GP DP SU
Sampler
SET VALUE
READ VALUE
Main Unit [1SF32 Ver. 00-05] [1SF32 Ver. 00-05] Complete
Loader [2SF31 Ver. 00-01] [2SF31 Ver. 00-01] Complete
D-I/O [3SF31 Ver. 00-00] [3SF31 Ver. 00-00] Complete
Sampler Unit [4SF31 Ver. 00-09] [4SF31 Ver. 00-09] Complete
Set
Set
Set
Set
Quit

Figure 8-28: Version Check Screen
(Actual values displayed on your system may vary from these values.)

(3) Press [Quit] to end the Version Check program.

(4) If the read values do not match to the set values, in case when the program version has been updated, "Error" appears on the right of the corresponding value.

(5) Verify that the program version displayed in READ VALUE column is correct, and press [Quit]. The version check confirmation window will appear.

Pressing [Set] registers the read check sum values as new set values.
Pressing [Cancel] ends the program without updating the check sum values.
Pressing [Continue] returns to the version check screen.

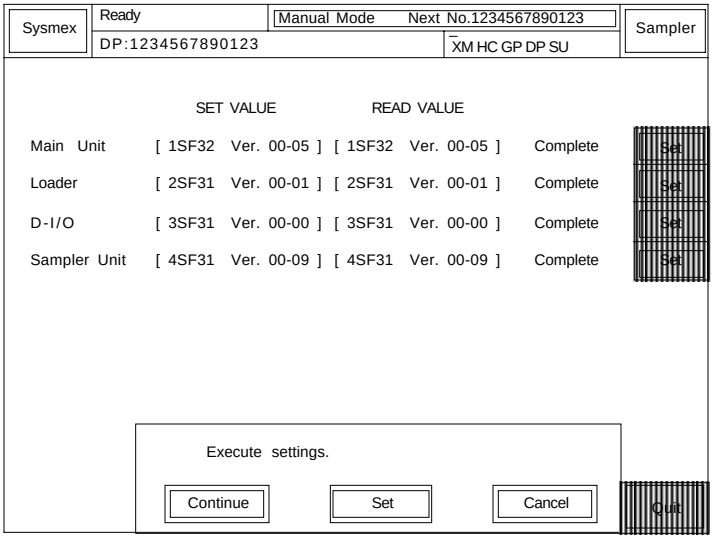


Figure 8-29: Version Check Confirmation Window

3.14 Service Data

Use this program to display the latest sample service data in the current display mode, and to display and reset the counters which indicate the number of operations each unit has performed.
The Service Data consists of three pages: "P1. WBC", "P2. RBC/PLT" and "P3. Counters" and can be changed by pressing [←] and [→] keys.

(1) Press [Mainte.] keypad in the root menu. The maintenance second menu will be displayed.

NOTE: If the [Mainte.] keypad is not displayed on the LCD, press [More] key to change the displayed root menu.

Figure 8-30: Maintenance Second Menu Screen

(2) Select [Service Data] from the maintenance second menu. The first page screen WBC data for the latest sample will be displayed.

(3) Use [←] and [→] keys to display "P2. RBC/PLT" or "P3. Counters".

(4) Press [Return] to exit the program.

P1. WBC

This program displays the WBC data of the latest sample.

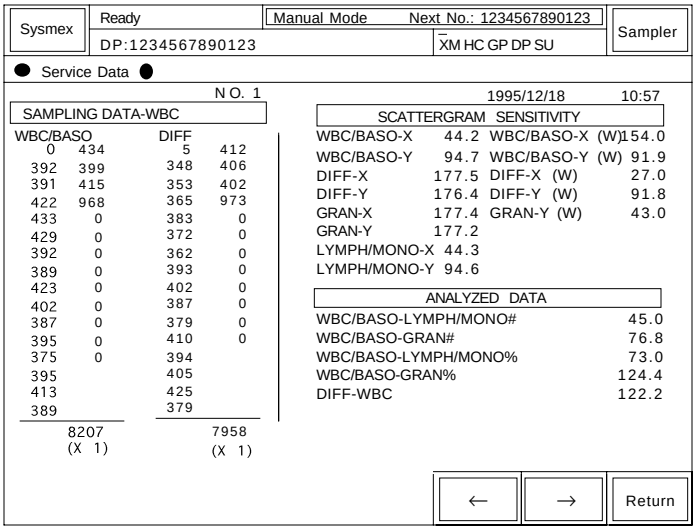


Figure 8-31: Service Data - WBC Screen

1) Sampling Data - WBC

In the WBC/BASO and DIFF columns, cell counts taken every 0.5 seconds are displayed. These cell count displays are for monitoring the occurrence of sudden noise. If the ratio of the difference between the maximum and minimum cell count to the total sampling cell count is outside the specified range, a "Sampling Error" message (analysis error) will be displayed. The total cell counts displayed are limited by the display digit to 4-figures. Multiply these values by the number in parentheses at the bottom of the column to obtain the actual total cell count value.

2) Scattergram Sensitivity

WBC/BASO-X : Most frequently occurring value for the WBC/BASO X-axis channel. (Unit: fL)

WBC/BASO-Y : Most frequently occurring value for the WBC/BASO Y-axis channel. (Unit: fL)

DIFF-X : Most frequently occurring value for the DIFF X-axis channel. (Unit: fL)

DIFF-Y : Most frequently occurring value for the DIFF Y-axis channel. (Unit: fL)

GRAN-X : Most frequently occurring value for the GRAN area in DIFF X-axis channel. (Unit: fL)

GRAN-Y : Most frequently occurring value for the GRAN area in DIFF Y-axis channel. (Unit: fL)

LYMPH/MONO-X : Most frequently occurring value for the LYMPH/MONO area in WBC/BASO X-axis channel. (Unit: fL)

LYMPH/MONO-Y : Most frequently occurring value for the LYMPH/MONO area in WBC/BASO Y-axis channel. (Unit: fL)

WBC/BASO-X (W) : The arithmetic distribution width measured at the 50% level when the peak (WBC/BA-X) is equivalent to 100% for the WBC/BASO X-axis channel.

WBC/BASO-Y (W) : The arithmetic distribution width measured at the 50% level when the peak (WBC/BA-Y) is equivalent to 100% for the WBC/BASO Y-axis channel.

DIFF-X (W) : The arithmetic distribution width measured at the 50% level when the peak (DIFF-X) is equivalent to 100% for the DIFF X-axis channel.

DIFF-Y (W) : The arithmetic distribution width measured at the 50% level when the peak (DIFF-Y) is equivalent to 100% for the DIFF Y-axis channel.

GRAN-Y (W) : The arithmetic distribution width measured at the 50% level when the peak (GRAN-Y) is equivalent to 100% for the GRAN area in DIFF Y-axis channel.

3) Analyzed Data

WBC/BASO-LYMPH/MONO# : Count of cells counted in the Lymph/Mono area in the WBC/BASO channel.

WBC/BASO-GRAN# : Count of cells counted in the Granulocyte area in the WBC/BASO channel.

WBC/BASO-LYMPH/MONO% : Ratio of cells counted in the Lymph/Mono area in the WBC/BASO channel.

WBC/BASO-GRAN% : Ratio of cells counted in the Granulocyte area in the WBC/BASO channel.

DIFF-WBC : Count of cells counted in the WBC area in the DIFF channel.

P2. RBC/PLT

This program displays the RBC/PLT data of the latest sample.

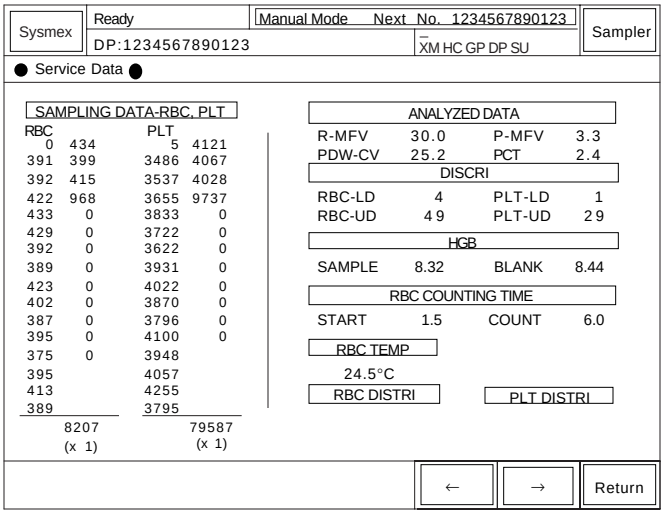


Figure 8-32: Service Data - RBC/PLT Screen

1) Sampling Data - RBC/PLT

In the RBC and PLT columns, cell counts taken every 1 second are displayed. These cell count displays are for monitoring the occurrence of sudden noise. If the ratio of the difference between the maximum and minimum cell counts to the total sampling cell count is outside the specified range, a "Sampling Error" message (analysis error) will be displayed. The total cell counts displayed are limited by the display digit to 4-figures. Multiply these values by the number in parentheses at the bottom of the column to obtain the actual total cell count value.

2) Analyzed Data

R-MFV	:	Most frequently occurring value in the RBC distribution in the RBC X-axis channel. (Unit: fL)
P-MFV	:	Most frequently occurring value in the PLT distribution in the PLT X-axis channel. (Unit: fL)
PDW-CV	:	PLT distribution width (CV method). (Expressed as %)
PCT	:	Platelet-crit. (Expressed as %)

3) DISCRI.

RBC-LD	:	The position of Lower Discriminator (LD) for the RBC is indicated with the bin number between 0 and 49.
PLT-LD	:	The position of Lower Discriminator (LD) for the PLT is indicated with the bin number between 0 and 49.
RBC-UD	:	The position of Upper Discriminator (UD) for the RBC is indicated with the bin number between 0 and 49.
PLT-UD	:	The position of Upper Discriminator (UD) for the PLT is indicated with the bin number between 0 and 49.

4) HGB

SAMPLE	:	Optical density of A/D-converted sample.
BLANK	:	Optical density of A/D-converted blank.

5) RBC Counting Time

START	:	The time period that the ball float in the RBC manometer starts descending and reaches the Start level. (Unit: seconds)
COUNT	:	The time period that the ball float in the RBC manometer moves from the Start level to the Stop level. (Unit: seconds)

6) RBC Temperature

Temperature (°C) of RBC detector.

7) RBC Distribution

This item is marked with a cell size abnormality indicator if the RBC size distribution is abnormal. Refer to *Chapter 10, Section 7.4 Histogram Flags for the indicators.*

8) PLT Distribution

This item is marked with a cell size abnormality indicator if the PLT size distribution is abnormal. Refer to *Chapter 10, Section 7.4 Histogram Flags for the indicators.*

P3. Counter

This program displays the counters, which indicate the number of operations each unit has performed, to assist you in deciding when to perform service. After servicing, the counters can be reset using this screen.

(1) Press the [Reset] key on the right of each item to reset the counter to zero (0).

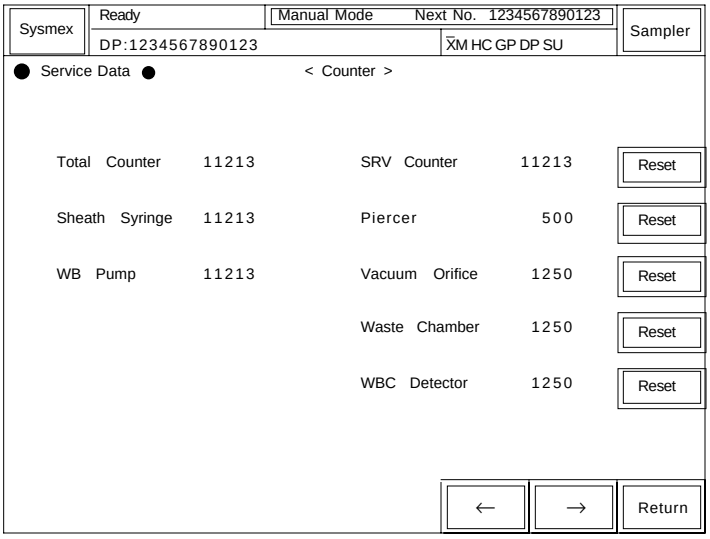


Figure 8-33: Service Data - Counters Screen

(2) Press [Return] key. The confirmation message window will appear.

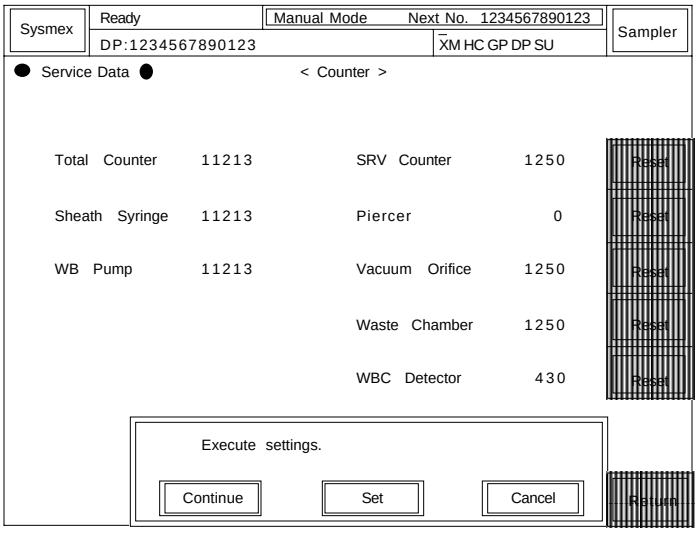
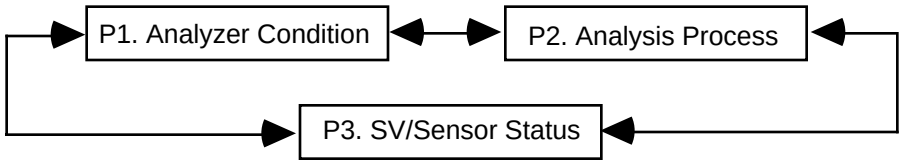


Figure 8-34: Counter Reset Confirmation Screen

(3) Press [Continue] to return to the Counter screen.
Press [Set] to reset the counter.
Press [Cancel] to cancel the counter reset and exit the Service Data program.

4. STATUS DISPLAY

Use this program to check status of the system at any time. (This program does not display analysis errors.)
The Status Display consists of three pages: "P1. Analyzer Condition", "P2. Analysis Process" and "P3. SV/Sensor Status" and can be changed by pressing the [←] and [→] keys.



(1) Press [Status Display] keypad in the root menu. The first page screen "Analyzer Condition" will be displayed.

(2) Use [←] and [→] keys to display "P2. Analysis Process" or "P3. SV/Sensor Status".

(3) Press [Return] to exit the program.

P1. Analyzer Condition

Use this page for checking memory status of stored samples. The current abnormal condition of peripherals when detected are indicated with the messages listed below.

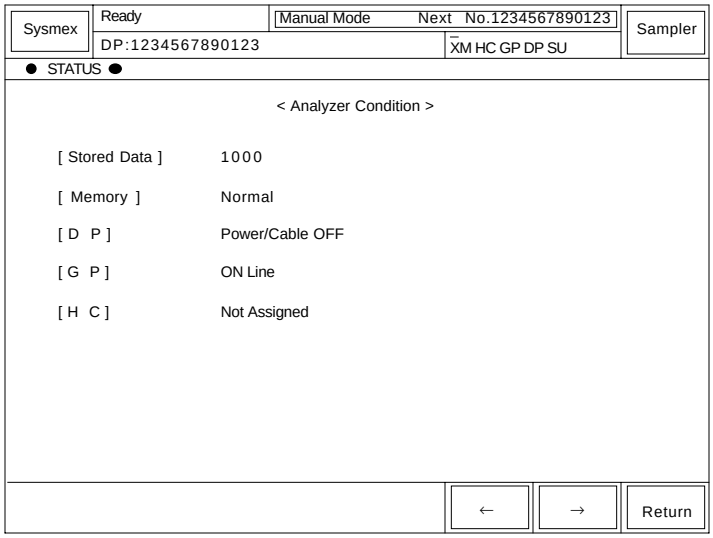


Figure 8-34: Status Display - Analyzer Condition Screen

[Stored Data] : Total number of stored data is displayed.

The following error status messages will be displayed.

NOTE: Only some of these messages are displayed in the error message display area in the System Status Area when occurred.

[Memory] : "Sum Error (BBM)", "Sum Error (EEPROM)", "Mem Unstorageable", "Seq. No. Overflow", "Control Table Error"

[DP] : "Not Assigned", "Power/Cable OFF", "Off Line", "Paper Empty", "Device Error"

[GP] : "Not Assigned", "Power/Cable OFF", Off Line/Dev.Error", "Paper Empty"

[HC] : "Not Assigned", "Off Line", "Ack Time Out", "Ack Code Error", "Not Transmissible"

P2. Analysis Process

Sequential or overlap analysis of up to three samples can be carried out within the instrument. Analysis status of each sample is displayed on the "Analysis Process" screen. Normally, the status of the last 4 samples is displayed. The sample displayed in the left column is a newly analyzed sample and the status is updated every second. The sample is identified by sequence number, ID No. and rack position number on the top three lines of the matrix. A hyphen will appear in "RACK" if the sample is analyzed in Manual mode. The display has 10 processing steps.

The symbols used to report the status are shown below with their meaning:

○ : ENTRY	Step is expected.
◎ : RUN	Step is in progress.
● : FINISH NORMAL	Completed without error.
✕ : INTERRUPTION	Step is interrupted.
: FINISH ABNORMAL	Completed with error.
: (blank)	The process has not begun.

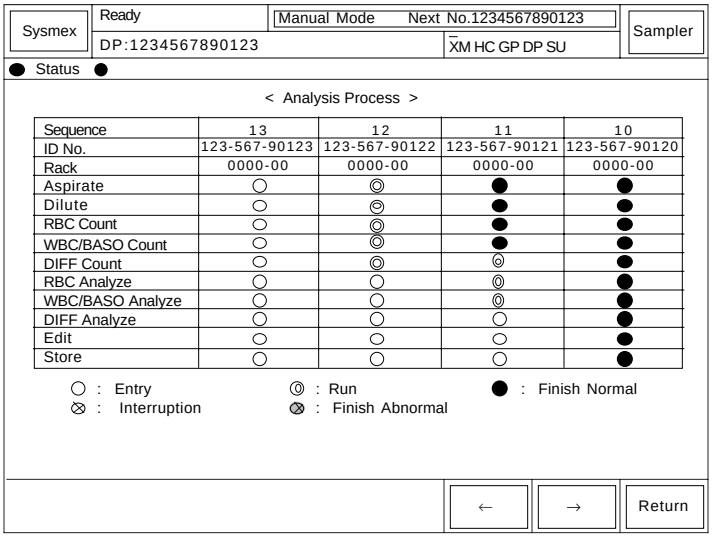


Figure 8-35: Status Display - Analysis Process Screen

P3. Sensor Status

Use this program to check pressure and vacuum. Refer to *Chapter 9: Adjustment* for the procedures.

Also the status of the solenoid valves and sensors, and the temperature in each unit can be observed using this screen.
The SV (solenoid valve) number displayed in yellow back-light is in the ON status.
The sensor number displayed in green back-light is in the ON status.
The SV/Sensor status is updated every second.

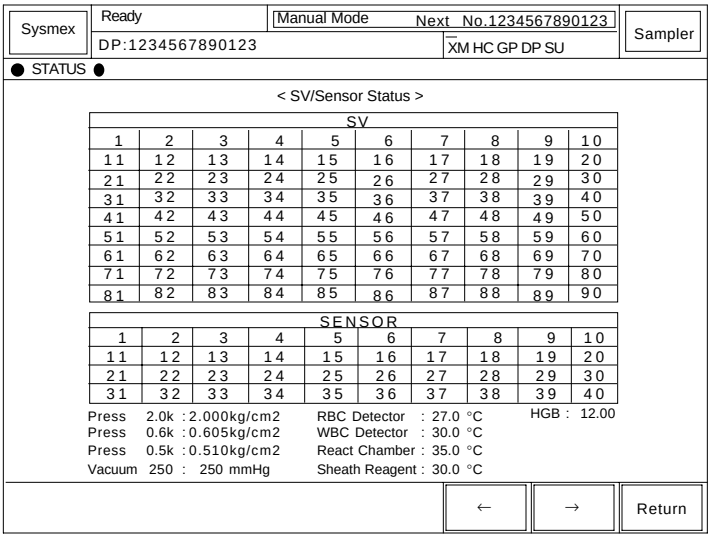


Figure 8-36: Status Display - SV/Sensor Status Screen

5. ERROR LOG

This program displays the list of past 189 errors and recovery messages. Use this program to display corrective action messages for the error messages.

NOTE: Analysis Error messages are not displayed on the Error Log screen.

(1) Press the [Sysmex] keypad in the left upper corner of the screen.

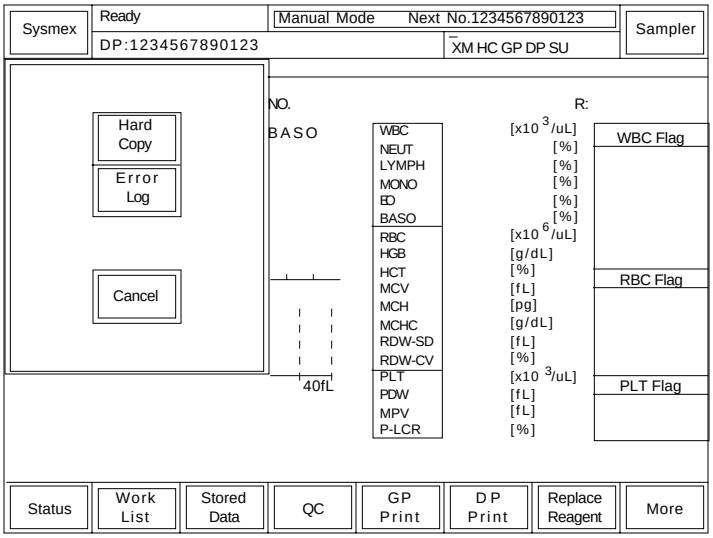


Figure 8-37: Sysmex Submenu window

(2) Press [Error Log] key from the submenu.

(3) The Error Log screen will appear.
A maximum of 21 messages can be displayed on the screen at one time.

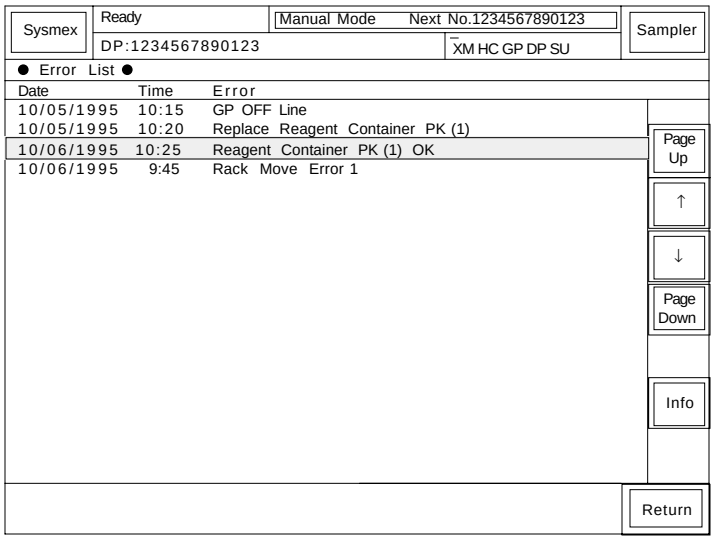


Figure 8-38: Error Log Screen

(4) Use the [↑] and [↓] keys to move the cursor to the error message, for which you want corrective action message.

(5) Press the [Info] keypad. The corrective action messages for the error the cursor is positioned on will be displayed. Take the actions suggested to correct the error.

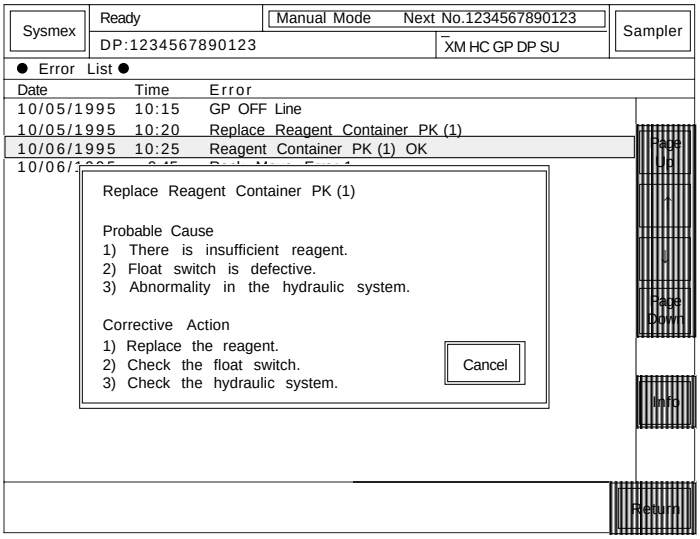


Figure 8-39: Error Information Screen

(6) Press [Return] to exit the program.

CHAPTER 9 ADJUSTMENT

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1. INTRODUCTION

From time to time it may be necessary to adjust certain components of the SF-3000 system. The Sysmex representative will perform initial adjusting; following that, the customer should adjust the instrument as described in the procedures provided in this chapter.

The following adjustment procedures have been included in this chapter.

- Pneumatic pressure (2.0 kg/cm^2)
- Main Unit pressure (0.6 kg/cm^2)
- Main Unit pressure (0.5 kg/cm^2)
- Main Unit vacuum (250 mm/Hg)
- LCD Contrast

2. PRESSURE/VACUUM DISPLAY

Pressure and vacuum from the Pneumatic Unit are adjusted by the Pneumatic Unit and Main Unit to 2.0 kg/cm^2, 0.6 kg/cm^2, 0.5 kg/cm^2 and 250 mmHg. These pressures and vacuum are monitored by sensors. If an error message is displayed, check the line connections for a leak. Afterwards, display the monitored value on the LCD and adjust the pressure or vacuum as described below.

2.1 Pneumatic Gauges

After you turn on the power and "Ready" appears on the LCD, check the pressure and vacuum level. The gauges on the front of the Pneumatic Unit show the pressure and vacuum. Adjustment is needed when the pressure does not conform to the requirements below. Vacuum cannot be adjusted in the Pneumatic Unit. See page 9-5.

Required Pressure/Vacuum

Pressure	1.8 kg/cm^2 or more
Vacuum	400 mmHg or more

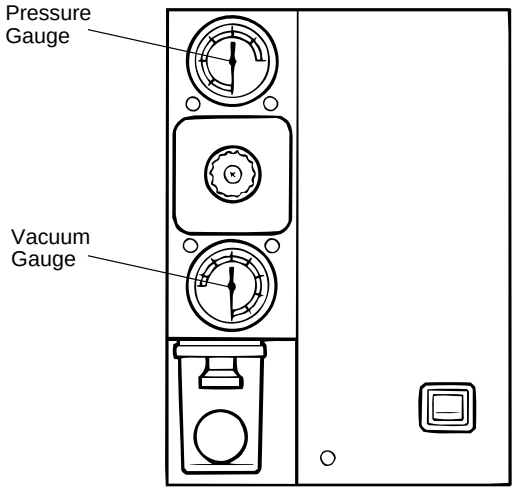

Figure 9-1: Pneumatic Gauges (Pneumatic Unit - Front)

2.2 Displaying the Monitored Values on the LCD

(1) Press the [Status] keypad in the root menu.

> **NOTE:** If the [Status] key is not displayed on the screen, press [More] key to change the displayed root menu.

(2) Switch the screen to "P3. SV/Sensor Status" using the [→] and [←] keys. The pressure and vacuum readings are displayed as shown in Figure 9-2.

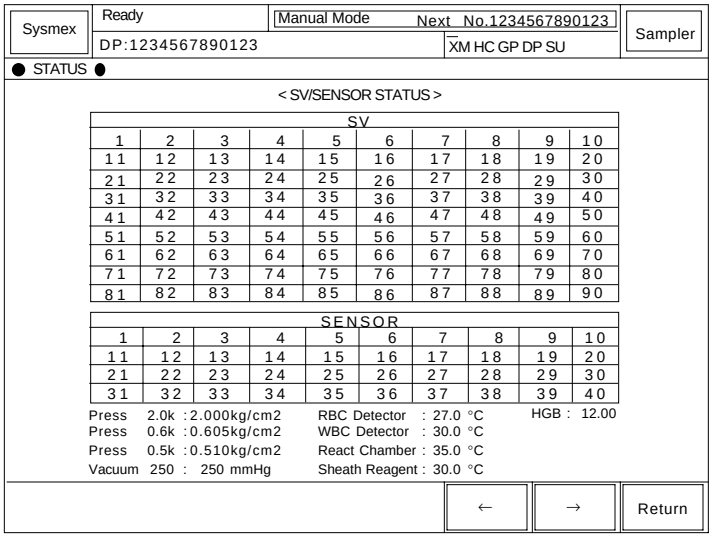

Figure 9-2: SV/Sensor Status Display

3. PNEUMATIC UNIT ADJUSTMENT

If the pressure is lower than the required 1.8 kg/cm^2, check for the following items and adjust as necessary.

- Leaks or cracks in connectors
- Blockage or pinching in pneumatic lines

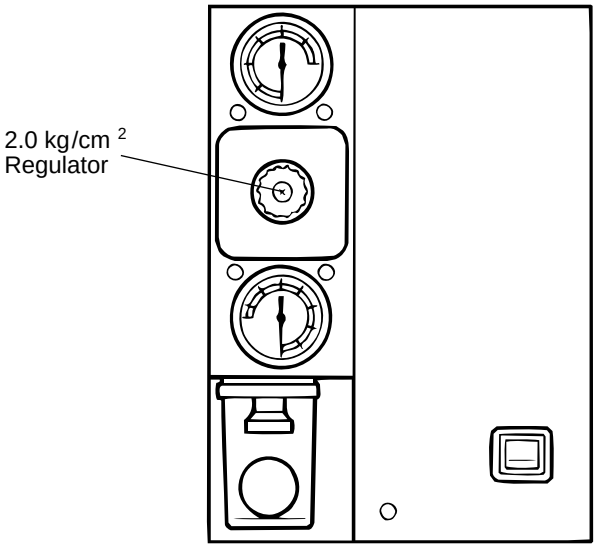

Figure 9-3: 2.0 kg/cm^2 Regulator (Pneumatic Unit - Front)

3.1 Adjusting the 2.0 kg/cm^2

This pressure is used to drive the sampling valve and master valves.

(1) Check the pressure level on the Pressure Gauge. The required pressure level is 1.8 kg/cm^2 or higher .

(2) Display the 2.0 kg/cm^2 pressure on the LCD (refer to *Section 2.2* in this chapter).

CAUTION: If the pressure levels on the pressure gauge and LCD display show 0.3 kg/cm^2 or more discrepancy, check the line connections for a leak.

(3) Loosen the lock screw of the adjustment knob for the 2.0 kg/cm^2 regulator using a Phillips screwdriver. See Figure 9-4.

(4) Turn the knob until the pressure displayed on the LCD falls within 2.0 ± 0.1 kg/cm^2. Turning the knob clockwise increases the pressure.

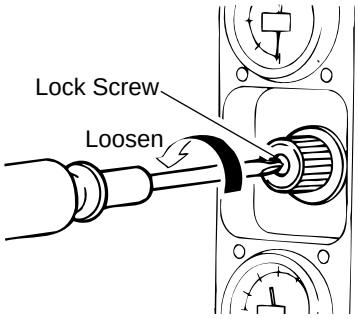

Figure 9-4: Loosen the Lock Screw

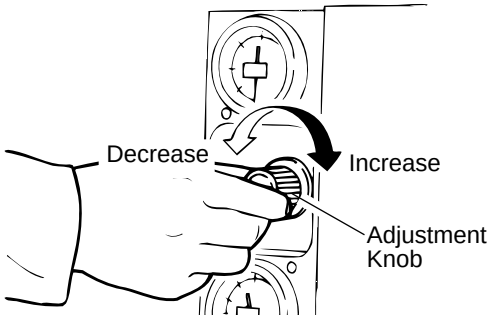

Figure 9-5: Turn the Adjustment Knob

CAUTION:
- Adjust the 2.0 kg/cm^2 pressure displayed on the LCD. Do not check the pressure level on the gauge for adjustment.
- Always adjust the pressure from a level that is below the target. If the pressure is high, decrease it all at once to a value that is below the target; then gradually increase it to the target.

NOTE: The required range for normal operation is within 1.8-2.3 kg/cm^2.

(5) When completing the adjustment, tighten the lock screw on the top of the regulator knob.

3.2 Adjusting the Vacuum

The vacuum cannot be adjusted in the Pneumatic Unit. If the vacuum falls below 400 mmHg, take the following steps.

(1) Pinch the tubing that runs from the Pneumatic Unit to the Main Unit. If the vacuum increases to 400 mmHg or more, a leak exists in the Main Unit. Contact a Sysmex service representative.

(2) Check the above tubing and Pneumatic Unit internal tubing. If any of them is disconnected, firmly reconnect it.

NOTE:	As instrument usage increases, the vacuum gradually decreases. In such cases, the vacuum pump and/or compressor gaskets may need to be repaired or replaced. Contact a Sysmex service representative.

4. MAIN UNIT ADJUSTMENT

Adjust the pressure and vacuum in the Main Unit to 0.6 kg/cm^2, 0.5 kg/cm^2 and 250 mmHg.

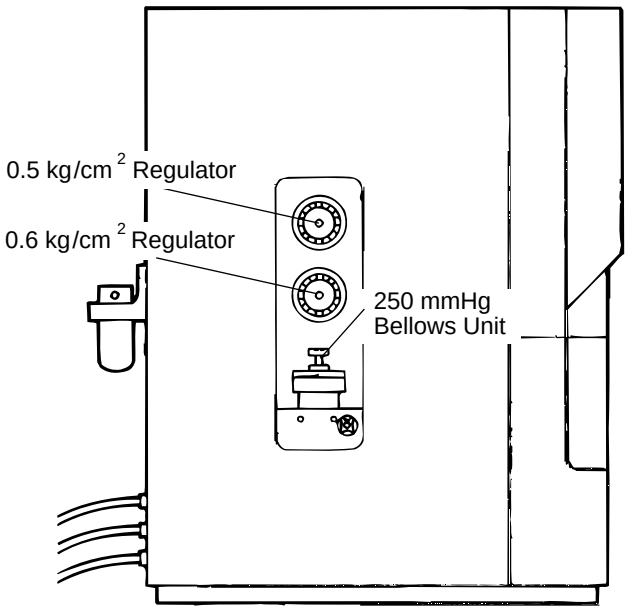

Figure 9-6: Regulators Location (Main Unit Left Side View)

4.1 Adjusting to 0.6 kg/cm^2

This pressure is supplied to the sheath detector for WBC analysis.

CAUTION: Before adjusting the 0.6 kg/cm^2, check the 2.0 kg/cm^2 pressure and adjust if necessary.

(1) Display the 0.6 kg/cm^2 pressure on the LCD (refer to *Section 2.2* in this chapter).

(2) Pull out the adjustment knob for the 0.6 kg/cm^2 regulator to release the lock.

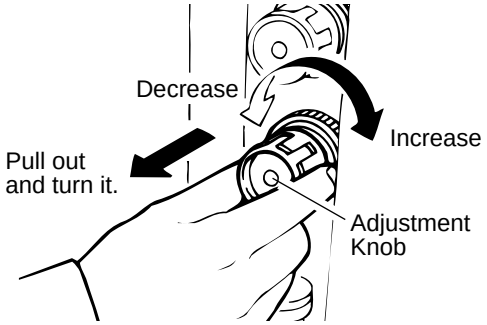

Figure 9-7: 0.6 kg/cm^2 Regulator

(3) Turn the knob until the pressure is within 0.6 ± 0.005 kg/cm^2. Turning the knob clockwise increases the pressure.

CAUTION: Always adjust the pressure from a level that is below the target. If the pressure is high, decrease it all at once to a value that is below the target; then gradually increase the level to the target.

NOTE: The required range for normal operation is within 0.6 ± 0.03 kg/cm^2.

(4) Press the knob in. This locks the regulator.

4.2 Adjusting to 0.5 kg/cm^2

This pressure is used to empty the waste chambers and provide mixing bubbles for sample dilutions.

CAUTION: Before adjusting the 0.5 kg/cm^2, check the 2.0 kg/cm^2 pressure and adjust if necessary.

(1) Display the 0.5 kg/cm^2 pressure on the LCD (refer to *Section 2.2* in this chapter).

(2) Pull out the adjustment knob for the 0.5 kg/cm^2 regulator to release the lock.

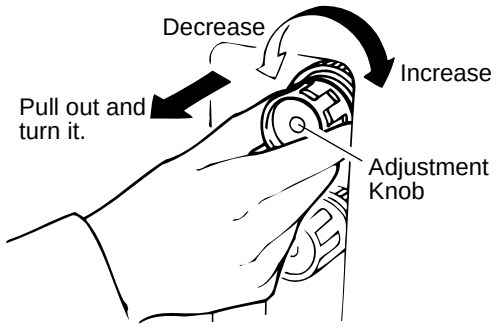

Figure 9-8: 0.5 kg/cm^2 Regulator

(3) Turn the knob until the pressure is within 0.5 ± 0.01 kg/cm^2. Turning the knob clockwise increases the pressure.

CAUTION: Always adjust the pressure from a level that is below the target. If the pressure is high, decrease it all at once to a value that is below the target; then gradually increase the level to the target.

NOTE: The required range for normal operation is 0.5 ± 0.03 kg/cm^2.

(4) Press the knob in. This locks the regulator.

4.3 Adjusting the 250 mmHg Vacuum

Vacuum is used to aspirate the sample and to drive the manometers.

(1) Display the 250 mmHg vacuum on the LCD (refer to *Section 2.2* in this chapter).

(2) Check the vacuum level on the Vacuum Gauge. The required vacuum level is 400 mmHg or more.

CAUTION: If the vacuum level on the vacuum gauge shows lower than 400 mmHg, check the line connections for a leak.

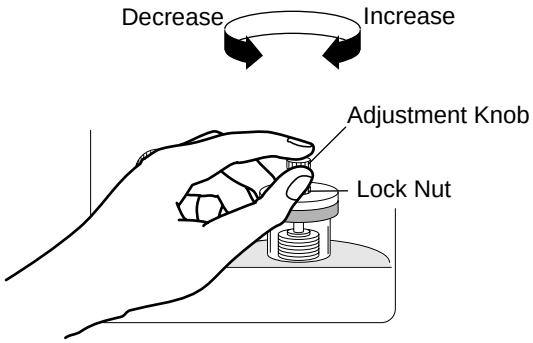

Figure 9-9: Bellows Unit

(3) Loosen the lock nut for the bellows unit.

(4) Turn the adjustment knob until the vacuum is within 250 ± 10 mmHg. Turning the knob clockwise increases the vacuum.

CAUTION: Always adjust the vacuum from a level that is below the target. If the vacuum is high, decrease it all at once to a value that is below the target; then gradually increase the level to the target.

NOTE: The required range for normal operation is 250 ± 20 mmHg.

(5) After completing the adjustment, re-tighten the lock nut.

5. LCD CONTRAST ADJUSTMENT

NOTE: The LCD contrast will automatically decrease when there is not key operation for 5 minutes. Touch anywhere on the LCD to recover. Refer to *Chapter 1, Section 9: LCD Screen*

(1) Open the front cover of the Main Unit and set the stop bar in position.

CAUTION: When working with the front cover open, make sure that the stop bar is in place to avoid closing accidentally.

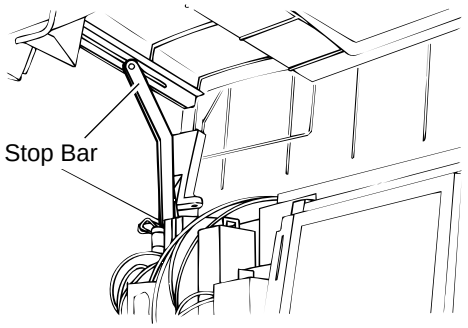

Figure 9-10: Set the Stop Bar

(2) The contrast control knob for the screen is located at the right bottom of the LCD. Refer to Figure 9-11 for the location of the control knob.

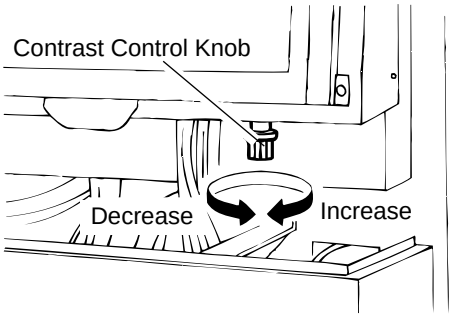

Figure 9-11: Contrast Controller

(3) Turn the control knob. Turning the knob counterclockwise (when viewed from the knob top) increases the contrast.

(4) Release the stop bar and close the front cover.

6. ID BAR CODE READER ADJUSTMENT (Option)

NOTE: When adjusting the ID Bar-Code Reader, contact your Sysmex service representative for his/her instruction and assistance.

(1) Pull out the Sampler Unit by approx. 10 cm, and remove the Main Unit Front Panel-B Assy.

CAUTION:
- DO NOT open the front panel or try to remove the Sampler Unit without instruction and assistance of Sysmex service representative.
- DO NOT pull the Sampler Unit more than 10 cm to avoid tubing disconnection.

(2) Push and refit the Sampler Unit.

CAUTION: When refit the Sampler Unit, take care not to pinch the tubing.

(3) Prepare the sample racks containing blood collection tubes with the 2 mm wide ID bar-code labels attached properly. See Figure 9-12.

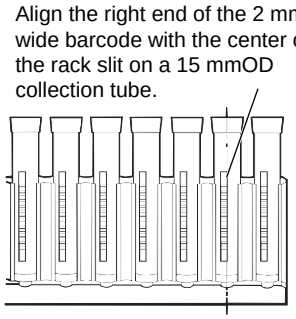

Figure 9-12: Affixing the Bar-Code Labels

(4) Perform the ID reader test program by pressing [Mainte.], [Test] and [ID Read] keypads. When "Set Rack and press Start Switch" appears, press the Start Switch. (Refer to *Chapter 8, Section 3.7: Test Bar Code Reader* for the procedures.)

(5) Verify that the ID bar-codes are read correctly.

(6) If the bar-code reading failed, adjust the position of the ID Reader.
Loosen the fixing screws A and B shown in Figure 9-13, and move the ID Reader screw B side while fixing the screw A position.

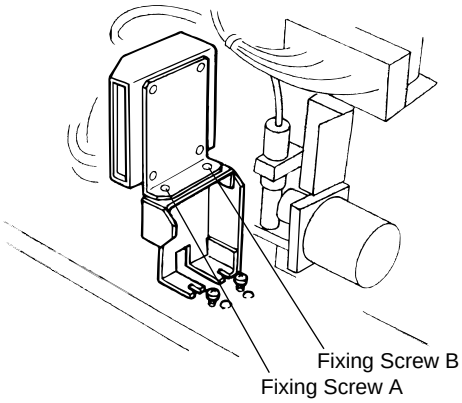

Figure 9-13: Adjusting the Bar-Code Reader Position

(7) Repeat the ID read test program to verify the bar-codes are read correctly.

(8) When the adjustment is complete, pull out the Sampler Unit by approx. 10 cm, and refit the Front Panel-B Assy.

(9) Refit the Sampler Unit.

CAUTION: When refit the Sampler Unit, take care not to pinch the tubing.

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1. INTRODUCTION

This chapter explains the detection principles, analysis methodology, individual analysis procedures, and hardware components employed by the SF-3000.

- **Detection Principles**
  Describes flow cytometry by means of semiconductor laser, DC detection method, and the SLS-hemoglobin method.

- **Analysis Flow**
  Explains Main Unit analysis flow and particle size distribution analysis.

- **Main Unit**
  Gives a functional description of the Main Unit along with component nomenclature.

- **Pneumatic Unit**
  Gives a functional description of the Pneumatic Unit along with component nomenclature.

- **Sampler Unit (Optional)**
  Gives a functional description of the Auto Sampler Unit and Manual CP Unit along with component nomenclature.

2. DETECTION PRINCIPLES

This section describes the flow cytometry by means of semiconductor laser and the DC (direct current) detection method for blood cell analysis.

2.1 Flow Cytometry by Semiconductor Laser

After a predetermined volume of blood is aspirated and diluted by a specific amount of reagent or diluent, it is injected into the flow cell (conical chamber) being surrounded with front sheath reagent of a particle-free fluid. This sheath flow method, also called Hydrodynamic Focusing, improves cell count accuracy and reproducibility. Because the blood cells pass through the center of the flow cell in a single file, the generation of abnormal cell pulses is prevented.

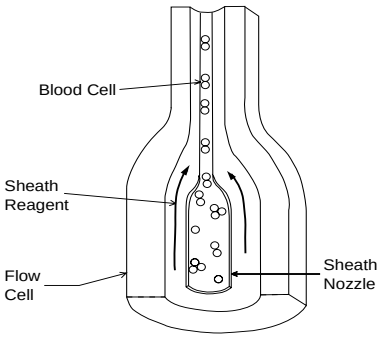


Figure 10-1: Flow Cell

When the blood cells are suspended in the diluent pass through the flow cell, the blood cells are radiated with rays from a laser beam, generating scattered light in intensities proportional to the size of blood cells. The low-angle (1-6°) scattered light reflects cell size, and the high-angle (8-20°) scattered light reflects intracellular density (nucleus size and density). The photo-diodes receive this scattered light and convert it into electrical pulses.

Data collected on the size of these pulses can be used to draw a 2-dimensional distribution (scattergram) of blood cell size and intracellular density. Various types of analysis data can then be obtained from the scattergrams.

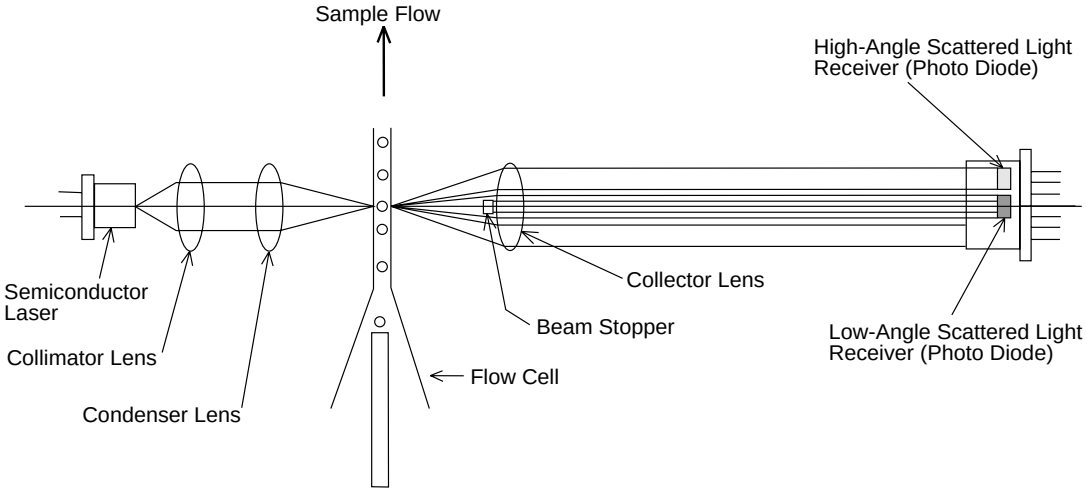


Figure 10-2: Scattered Light Measurement System

2.2 DC Detection Method

After a predetermined volume of blood is aspirated and diluted by a specific amount of reagent or diluent, it is sent to the RBC/PLT detection chamber. In the detection chamber, there is a small opening called an aperture. On each side of the aperture are electrodes through which flows direct current.
When blood cells are suspended in the diluent pass through the aperture, the direct current resistance between the electrodes changes. This resistance causes an electrical pulse change, which is proportional to the size of the blood cell.
Data collected on the size of these pulses can be used to draw a particle size distribution curve, which reflects the size of the blood cells. Various types of analysis data can then be obtained from these particle size distribution curves.

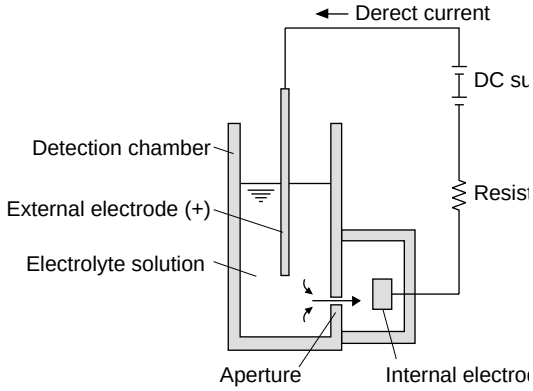


Figure 10-3: DC Measurement System

2.3 SLS-Hemoglobin

Conventionally, the most common automated method of measuring hemoglobin is the cyanmethemoglobin method. This method has both advantages and disadvantages when used with a fully automated instrument such as the SF-3000.

The cyanmethemoglobin method was recommended as the international standard in 1966 by the ICSH (International Committee for Standardization in Haematology). However, because the speed of hemoglobin transformation is slow, this method was deemed inappropriate for the quick processing of multiple samples by automation. Also, using cyanide, a toxic substance, requires special disposal of the waste fluid, making the method even less desirable.

The SLS-hemoglobin method makes use of the best parts of two methods: the oxyhemoglobin method and the cyanmethemoglobin method.
The SLS-hemoglobin method, as with the oxyhemoglobin method, is considered to be appropriate for automation because the transformation of blood hemoglobin is fast and non toxic substances are used.
Further, since methemoglobin can be analyzed, control samples such as blood containing methemoglobin can also be accurately analyzed.

In the SLS-Hg method, surfactants lyze the red blood cell membrane releasing hemoglobin. The globin group of the hemoglobin molecule is altered by the hydrophilic alkyl group of Sodium Lauryl Sulfate. This induces the conversion of hemoglobin from the ferrous (Fe^{+2}) to the ferric (Fe^{+3}) state forming methemoglobin which combines with Sodium Lauryl Sulfate to become SLS-Hb hemichrome molecule.

3. SAMPLE FLOW BLOCK DIAGRAM

WBC Analysis

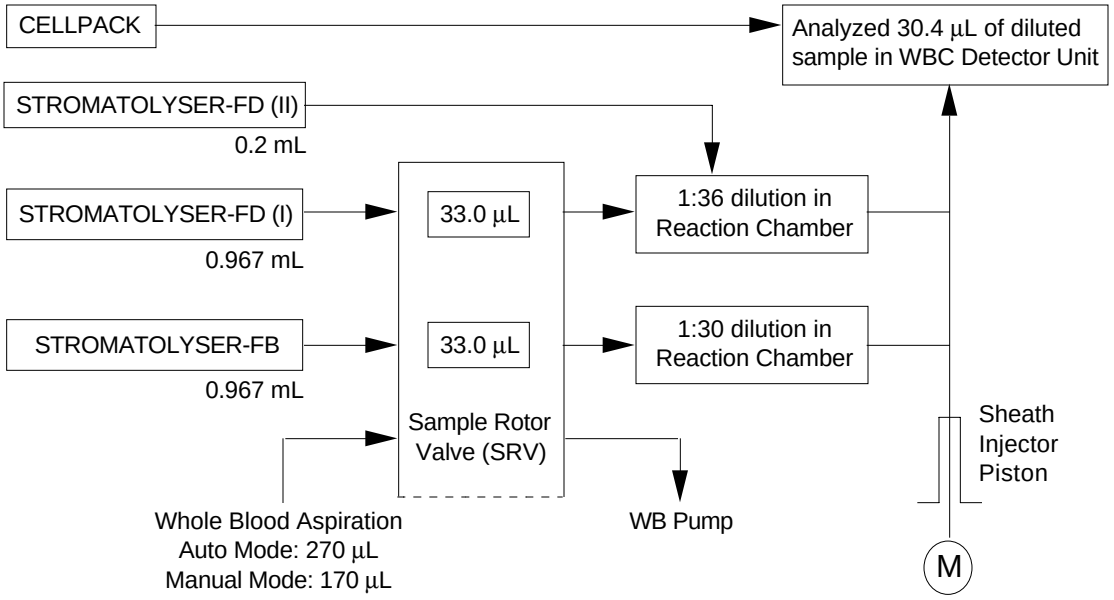


Figure 10-4: WBC Sample Flow

RBC/PLT/HGB Analysis

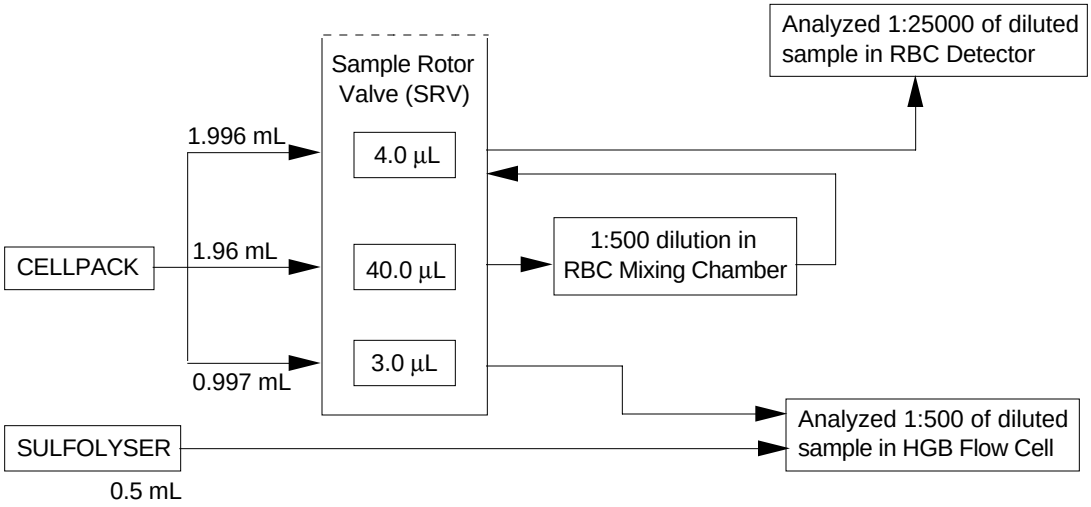


Figure 10-5: RBC/PLT/HGB Sample Flow

4. RBC/PLT/HGB ANALYSIS

4.1 RBC/PLT Analysis Flow

In RBC (red blood cell) and PLT (platelet) analyses, the number of red blood cells and platelets contained in the blood sample are counted. The following illustrates the procedure.

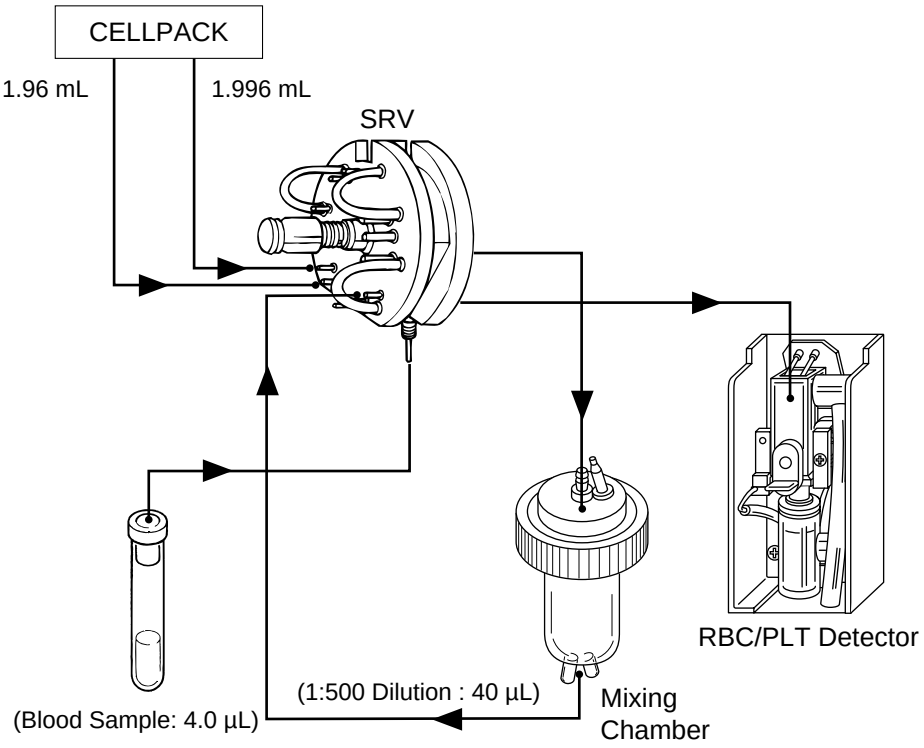


Figure 10-6: RBC/PLT Sample Flow

(1) The whole blood is aspirated from the whole blood aspiration tube to the sample rotor valve.

(2) The 4.0 µL sample (measured by the sample rotor valve) is diluted to 1:500 with 1.996 mL of diluent (CELLPACK), and then sent to the RBC sample mixing chamber.

(3) The 40.0 µL of the 1:500 diluted sample (measured by the sample rotor valve) is diluted to 1:25000 with 1.96 mL of diluent (CELLPACK), and then sent to the RBC/PLT detector.

(4) The RBC detector counts RBC and PLT by means of the DC detection method. At the same time, HCT (hematocrit) is measured by the cumulative pulse height detection method.

4.2 HGB Analysis Flow

In HGB (hemoglobin) analysis, the volume of hemoglobin contained in the blood sample is measured. The following illustrates the procedure.

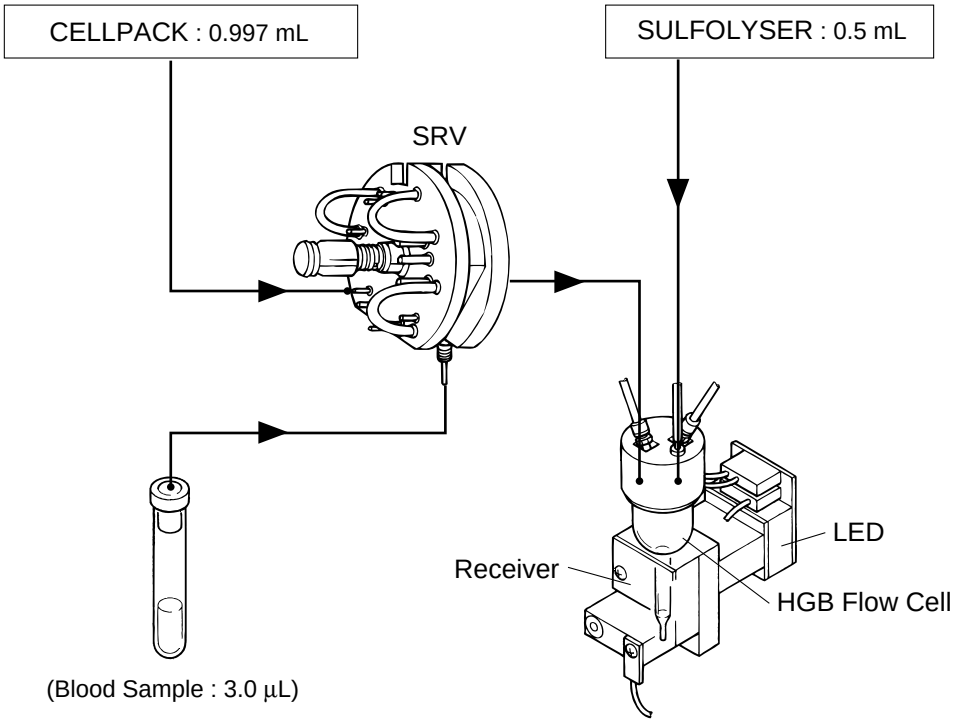


Figure 10-7: Hemoglobin Sample Flow

(1) The whole blood is aspirated from the whole blood aspiration tube to the sample rotor valve.

(2) The 3.0 µL sample (measured by the sample rotor valve) is diluted to 1:333 with 0.997 mL of diluent (CELLPACK). The diluted sample is then sent to the flow cell.
At the same time, 0.5 mL of the reagent used for the HGB determination (SULFOLYSER) is added to hemolyze the red cells and transform hemoglobin into SLS-hemoglobin. The final dilution ratio is 1:500.

(3) The light emitted at a 555 nm wavelength from the photo diode passes through the lens and is directed at the sample in the flow cell. The concentration of the SLS-hemoglobin is measured by its absorbance of light, as compared to the absorbance of the diluent (blank) measured before the sample entered the flow cell.

4.3 Red Blood Cell (RBC) Indices

Red blood cell constants (mean cell volume, mean cell hemoglobin, and mean cell hemoglobin concentration) are calculated from the RBC, HGB and HCT.

1. Mean Corpuscular Volume (MCV)

MCV is calculated from RBC and HCT as follows:

$$\text{MCV (fL)} = \frac{\text{HCT (\%)}}{\text{RBC (x10}^6/\mu\text{L)}} \times 10$$

2. Mean Corpuscular Hemoglobin (MCH)

MCH is calculated from RBC and HGB as follows:

$$\text{MCH (pg)} = \frac{\text{HGB (g/dL)}}{\text{RBC (x10}^6/\mu\text{L)}} \times 10$$

3. Mean Corpuscular Hemoglobin Concentration (MCHC)

MCHC is calculated from HGB and HCT as follows:

$$\text{MCHC (g/dL)} = \frac{\text{HGB (g/dL)}}{\text{HCT (\%)}} \times 100$$

5. WBC CLASSIFICATION

White blood cells (WBC) are generally classified as lymphocytes, monocytes, and granulocytes. Granulocytes are further subclassified as neutrophils, basophils, eosinophils. The SF-3000 uses the optical detector block incorporating the semiconductor laser to analyze the WBC population. This section explains the applicable analysis procedures.

5.1 4DIFF Analysis

In the DIFF channel, lymphocytes, monocytes, eosinophils and a group of neutrophils and basophils are analyzed to determine the WBC 4-differentials using the flow cytometry. The following illustrates the procedure.

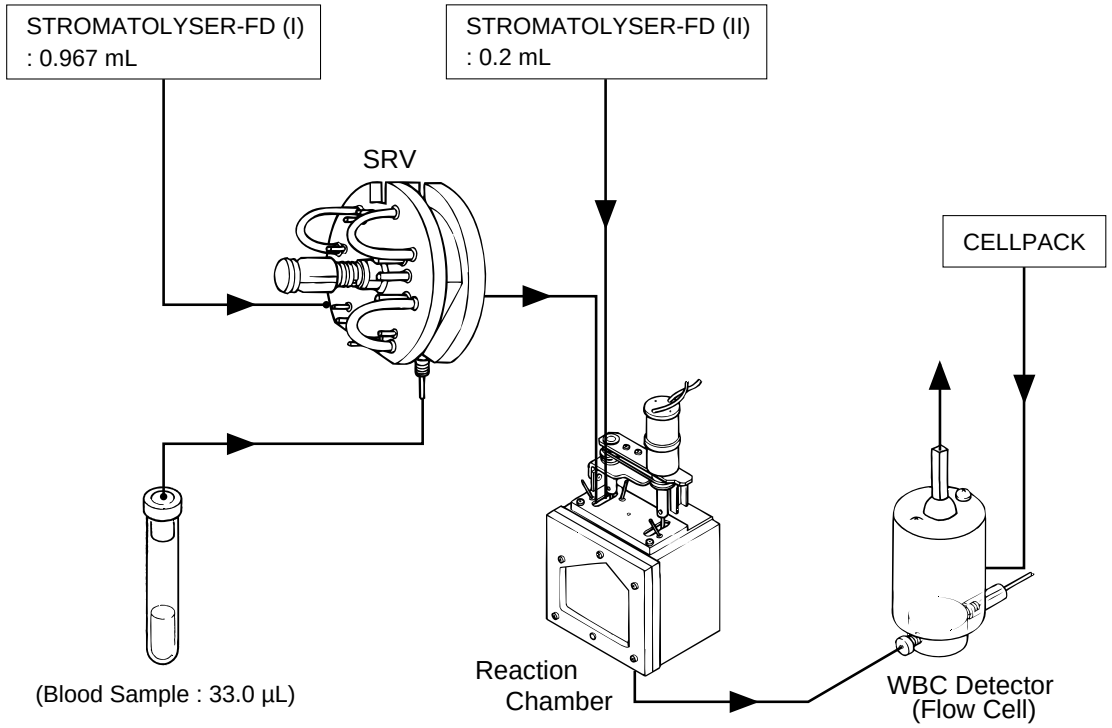


Figure 10-8: Differential Sample Flow

(1) The whole blood is aspirated from the whole blood aspiration tube to the sample rotor valve.

(2) The 33.0 µL sample (measured by the sample rotor valve) is transferred to reaction chamber. 0.967 mL of reagent (STROMATOLYSER-FD (I)) and then 0.2 mL of reagent (STROMATOLYSER-FD (II)) are added to make 1:36 dilution.

(3) During the approximately 8.5-second interval in the reaction chamber, the red blood cells are hemolyzed.

(4) The sheath injector piston slowly sends 30.4 µL of 1:36 diluted sample to the WBC-4DIFF detector; then the system, using the flow cytometry by means of semiconductor laser, performs the analysis.

5.2 WBC/BASO Analysis

Basophil determination and WBC number counting are performed in the WBC/BASO channel using the flow cytometry. The following illustrates the procedure.

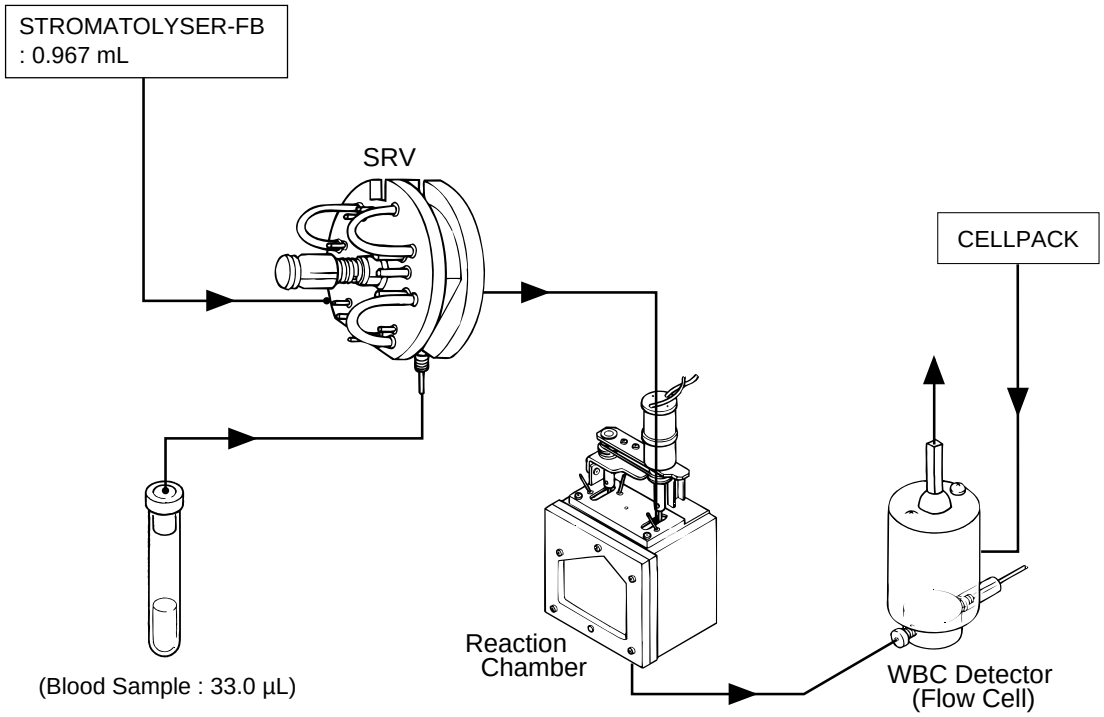


Figure 10-9: WBC/BASO Sample Flow

(1) The whole blood is aspirated from the whole blood aspiration tube to the sample rotor valve.

(2) The 33.0 µL sample (measured by the sample rotor valve) is transferred to reaction chamber. At the same time, 0.967 mL of reagent (STROMATOLYSER-FB) is added to make 1:30 dilution.

(3) During the approximately 31.5-second interval in the reaction chamber, the red blood cells are hemolyzed.

(4) The sheath injector piston slowly sends 30.4 µL of 1:30 diluted sample to the WBC/BASO detector; then the system, using the flow cytometry by means of semiconductor laser, performs the analysis.

6. WBC SCATTERGRAMS

The flow cytometry with semiconductor laser beam produces scattergrams that show 2-dimensional distributions of cell size and intracellular (size of nucleus, etc.) density.

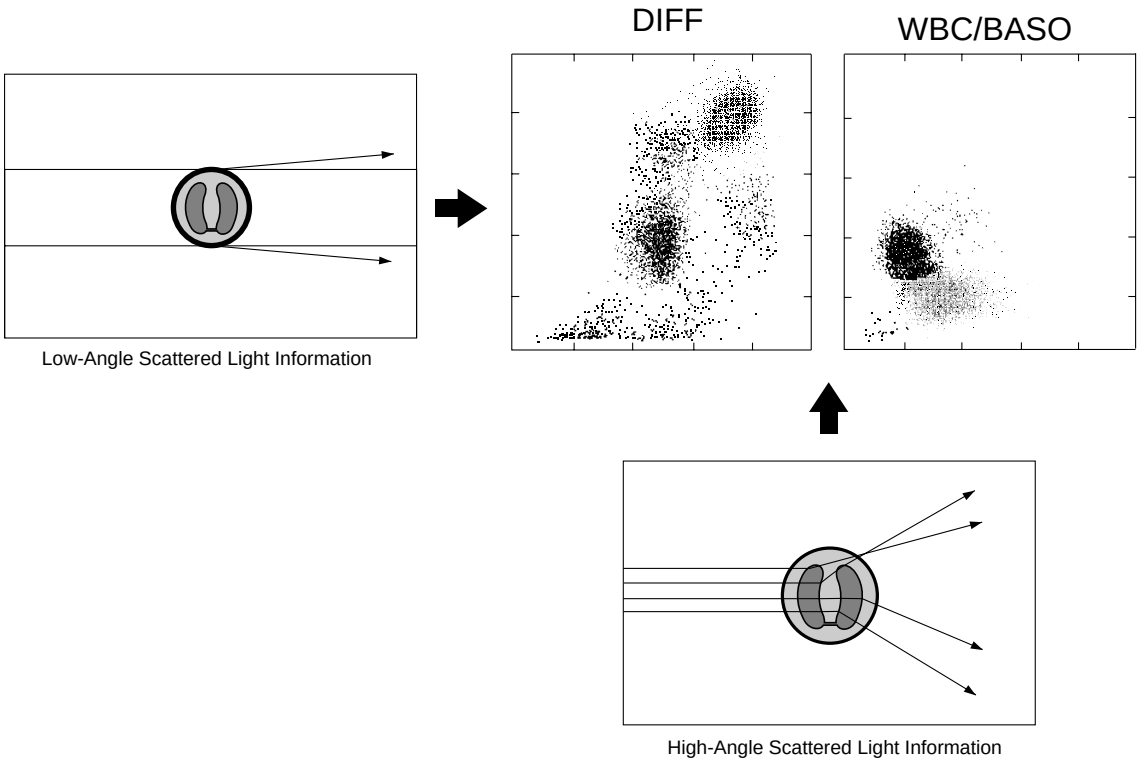


Figure 10-10: Scattergram Generation

The SF-3000 uses two channels, one for 4 DIFF analysis and the other one for WBC/BASO analysis.

The 4 DIFF analysis channel is used to classify red blood cell ghosts, lymphocytes, monocytes, eosinophils, and the group of neutrophils and basophils. The WBC/BASO analysis channel is used to classify red blood cell ghosts, basophils, the group of lymphocytes and monocytes, and the group of neutrophils and eosinophils.

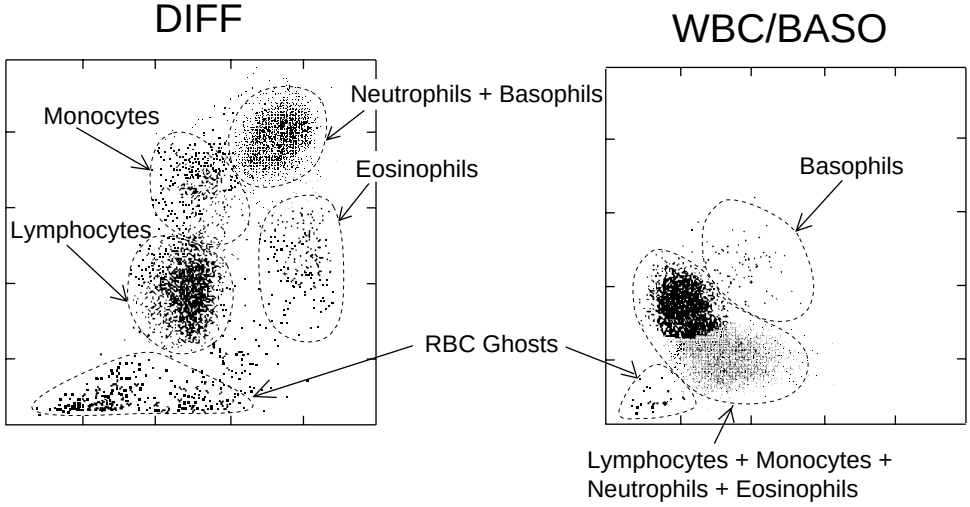


Figure 10-11: Cell Distribution

7. RBC/PLT PARTICLE SIZE DISTRIBUTION ANALYSIS

7.1 RBC Particle Size Distribution

The RBC (red blood cell) count is found by measuring the number of particles whose size is between a lower discriminator (LD) and an upper discriminator (UD), both of which are automatically adjusted in the ranges of 25-75 fL (femtoliters) and 200-250 fL, respectively. The particle size distribution is used to check the discriminator levels for abnormal relative height, the existence of two or more peaks, and the distribution width. The SF-3000 employs the following two methods to show the red blood cell distribution width (RDW).

1. RDW-SD

RDW-SD (RBC Arithmetic Distribution Width) is the arithmetic distribution width measured at the 20% level when the peak is equivalent to 100%. The RDW-SD is measured in fL (1 femtoliters = 10^{-15} liter).

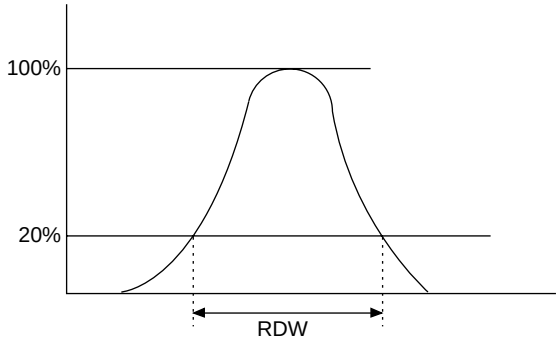


Figure 10-12: RDW-SD

2. RDW-CV

RDW-CV (RDW-Coefficient of Variation) uses the formula below to calculate L1 and L2, the points at which 68.26% of the area intersects the X-axis.

$$\text{RDW-CV}(\%) = \frac{SD}{MCV} \times 100 = \frac{L2-L1}{L2+L1} \times 100$$

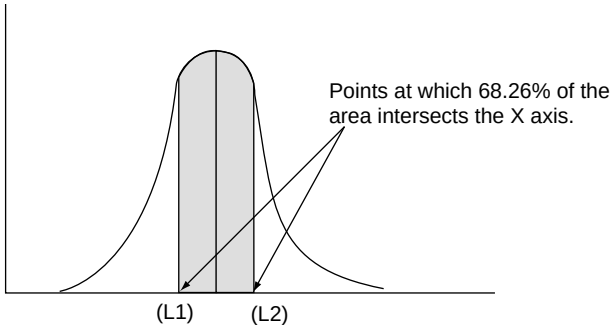


Figure 10-13: RDW-CV

7.2 PLT Particle Size Distribution

The PLT particle size distribution analysis is performed by using three discriminators. The lower discriminator (LD) is adjusted automatically in the 2-6 fL (femtoliter) size range; an upper discriminator (UD), in the 12-30 fL range; and a fixed discriminator (FD), at 12 fL (used for flagging purposes).
The PLT particle size distribution is used to check the relative height at the LD and UD, the distribution width, and the existence of two or more peaks.

1. Mean Platelet Volume (MPV)
MPV is calculated from the following formula.

$$\text{MPV (fL)} = \frac{\text{PCT(\%)}}{\text{PLT (x10}^3/\mu\text{L)}} \text{ x } 10000$$

PCT: Weighted frequency of PLT; called the plateletcrit or platelet volume ratio.

2. PLT Distribution Width (PDW)
PDW is the distribution width at the 20% level when the peak is equivalent to 100%. PDW is expressed in femtoliters (1 femtoliters = 10^{-15} liter).

3. Platelet-Large Cell Ratio (P-LCR)
P-LCR is the ratio of the large platelets found between the FD and UD discriminators. It is calculated by dividing the number of cells that fall in the range between the FD and UD, by the number of cells that fall in the range between the LD and UD.

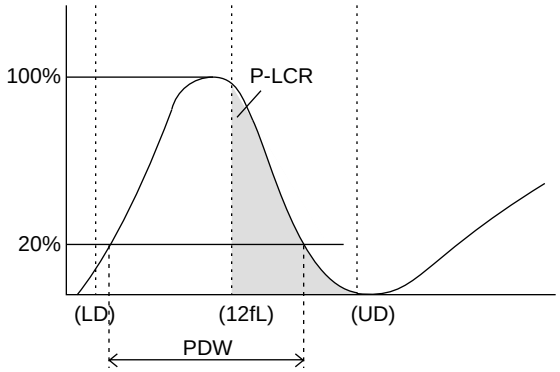


Figure 10-14: PDW/P-LCR

NOTE: *Customers in the United States:* Platelet Distribution Width (PDW) and Platelet Large Cell Ratio (P-LCR) parameters have not been approved for reporting by the Food & Drug Administration (FDA). The obtained values should be excluded from all print forms until reporting approval has been obtained. See *Chapter 11: System Setup* for information on excluding these values.

7.3 Particle Size Distribution Representation

The shape of a particle size distribution (histogram) changes according to the method of representation. The distribution width of the particle size distribution, in particular, can appear completely different, depending on how it is presented or drawn.

The SF-3000 employs two representation methods: a Relative Height Method (Normal Expression); and an Absolute Count with Normogram Representation (Dotted Normal Range), developed to permit the user to obtain more information directly from the particle size distribution.

1. Relative Height Representation Method

This representation method normalizes the particle size distribution, drawing the peak to full scale (maximum height when the histogram is displayed).

Features:
- Distributions of different counts can be viewed with the same scale.
- Distribution widths can be visually compared.

Applicable Display: RBC histogram and PLT histogram

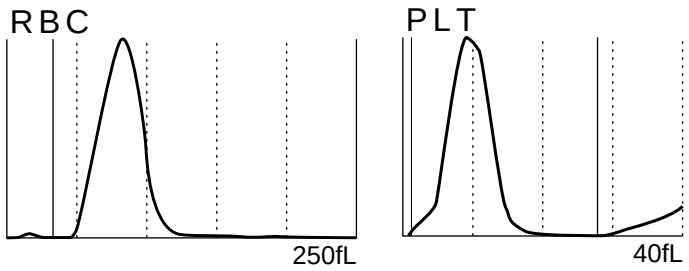


Figure 10-15: Relative Height Representation Method

2. Normogram Representation Method

This representation method expresses the peak of the histogram in relation to an empirical normogram (dotted normal range - normal particle size range). If the histogram is within or below the normogram, the normogram is displayed at full scale (100%). However, if the histogram peak is greater than the normogram, the histogram peak is displayed at 100%. In this case, the normogram becomes lower in proportion to the histogram peak. The normogram uses a 10 to 90 percentile range obtained by overlapping the histograms of a large number of patients.

Features:
- High/lower cell counts can be quickly visualized from the histogram.
- Abnormal histogram patterns can be quickly recognized when histograms differ from normograms.

Applicable Display: RBC histogram and PLT histogram when the Normal Range is set to be displayed. See *Chapter 11* for procedures.

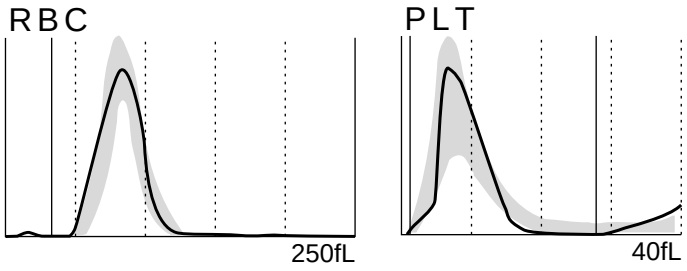


Figure 10-16: Normogram Representation Method

7.4 Histogram Flags

If the histogram is abnormal, one or more of the following error flags will appear.

NOTE: Histogram error flags are seen in the RBC/PLT system of the service data screen only. See *Chapter 8, Section 3.14: Service Data.*

RBC Histogram

LD: The relative height at the RBC lower discriminator exceeds the preset limit.
UD: The relative height at the RBC upper discriminator exceeds the preset limit.
DW: The RBC histogram does not cross the 20% height level twice, and the RDW-SD data is "---.-".
MP: Two or more RBC populations exist, and the RDW-SD data is "---.-".

PLT Histogram

LD: The relative height at the PLT lower discriminator exceeds the preset limit.
UD: The relative height at the PLT upper discriminator exceeds the preset limit.
DW: The PLT histogram does not cross the 20% height level twice, and the PDW data is "---.-".
MP: Two or more PLT populations exist, and the PDW data is "---.-".

8. MAIN UNIT ELECTRONIC SYSTEM

The Main Unit microprocessor controls the hydraulic system, solenoid valves and master valves; thus, it controls the flow of the sample, reagents, and waste fluid within the hydraulic system.

The signals received from the detector blocks are processed at the analog unit and sent to the microcomputer. There the analog signals are converted into digital signals, and processing is executed.

The RBC and PLT blood cell signals are processed at the analog unit and sent to the waveform processing circuits. Noise is removed and only required blood cell signals are produced. The microcomputer converts the digitized cell signals into histogram data, computes and displays the results, then stores data in memory.

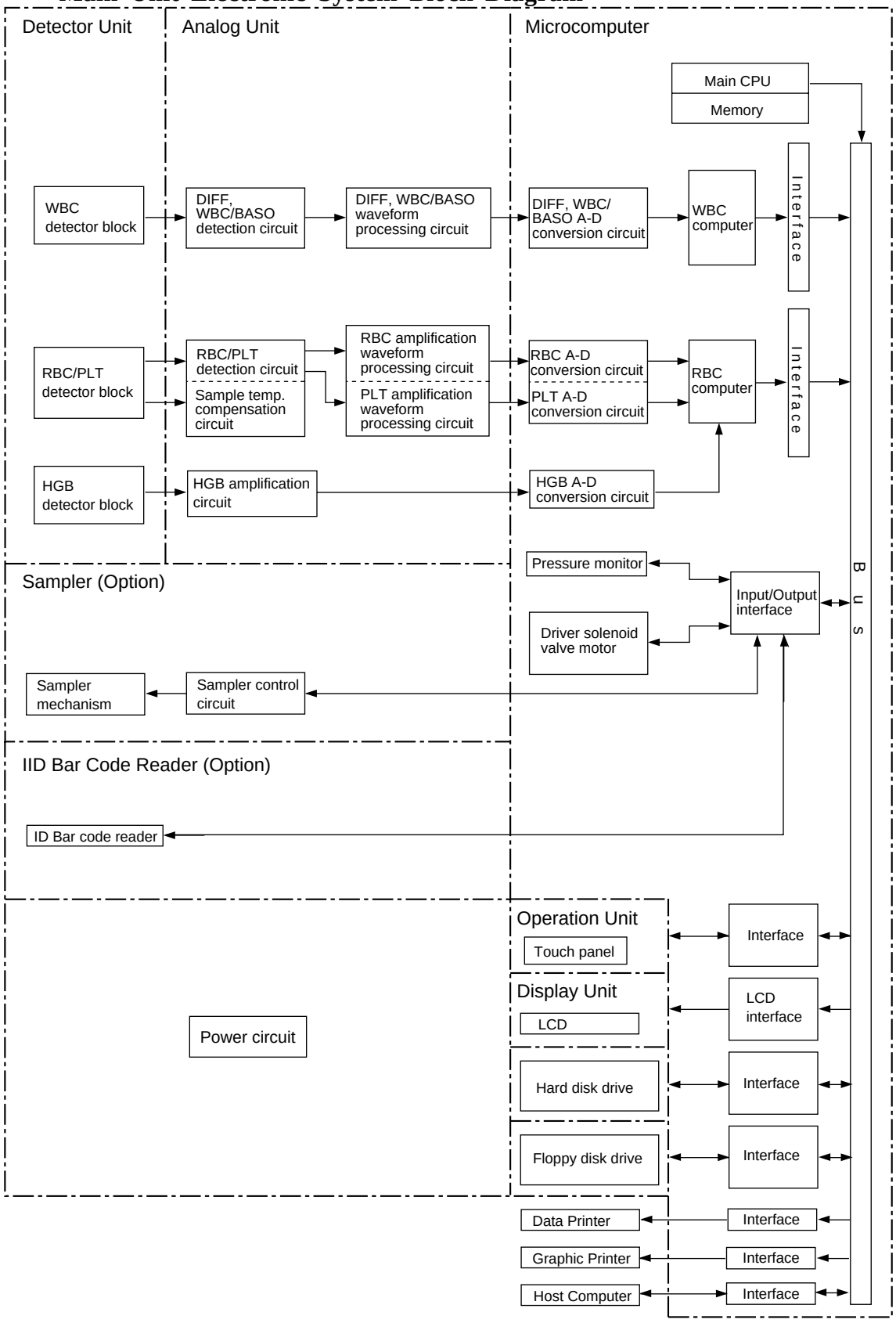
As for the cell signals from the 4DIFF channel and WBC/BASO channel, the low-angle and high-angle signals are sent to the waveform processing circuit, noise is removed to produce required blood cell signals. The microcomputer converts the digitized cell signals into histogram data, calculates, displays the results, and stores data in memory.

The HGB is calculated by deducting the absorbance of the diluent (blank) from the absorbance of the sample. Absorbance is computed as follows: Light that passes through the fluid is received by a photo diode, photoelectrically transformed, and converted into a digital signal. This signal is then sent to the RBC system computer, where the HGB data is computed.

The microprocessor computes the analyzed parameters; MCV, MCH, MCHC, RDW-SD, RDW-CV, PDW, P-LCR and MPV.

Altogether, the data from 23 parameters are displayed on the LCD screen. The instrument can output this data to external devices such as the host computer, data printer, graphic printer, and line printer.

Main Unit Electronic System Block Diagram



9. MAIN UNIT COMPONENTS

9.1 Front

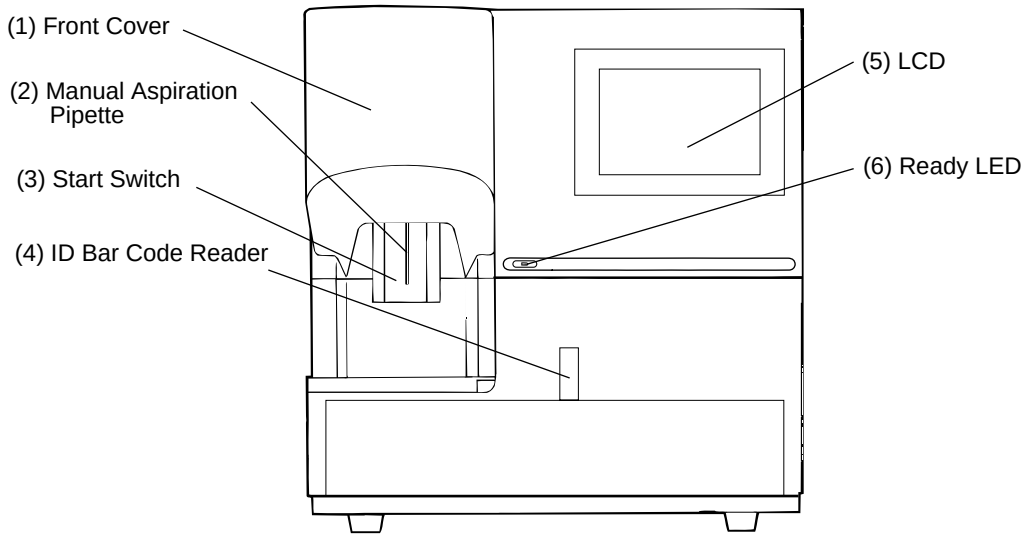


Figure 10-17: Main Unit – Front View

(1) Front Cover
Open the front cover by pulling and lifting up the panel with your hands. Open the cover to inspect or clean the Main Unit.

> **WARNING!** Use the stop bar and holder to prevent the cover from closing accidentally.

(2) Manual Aspiration Pipette
Used to aspirate a sample in manual and capillary modes.

(3) Start Switch
Press this switch to start analyzing in manual mode, capillary mode or closed mode.

(4) ID Bar Code Reader (Optional)
A bar code affixed to the collection tube or rack can be read during sampler analysis.

(5) LCD (Liquid Crystal Display)
Displays analysis and sample information, including analysis data, scattergrams and histograms, QC menus, action messages, etc. Touch panel is incorporated to transmit operational commands to the system and to view any pertinent information.

(6) Ready LED
Lights up when the Main Unit is "Ready" or "Sample Asp. Ready".

9.2 Rear

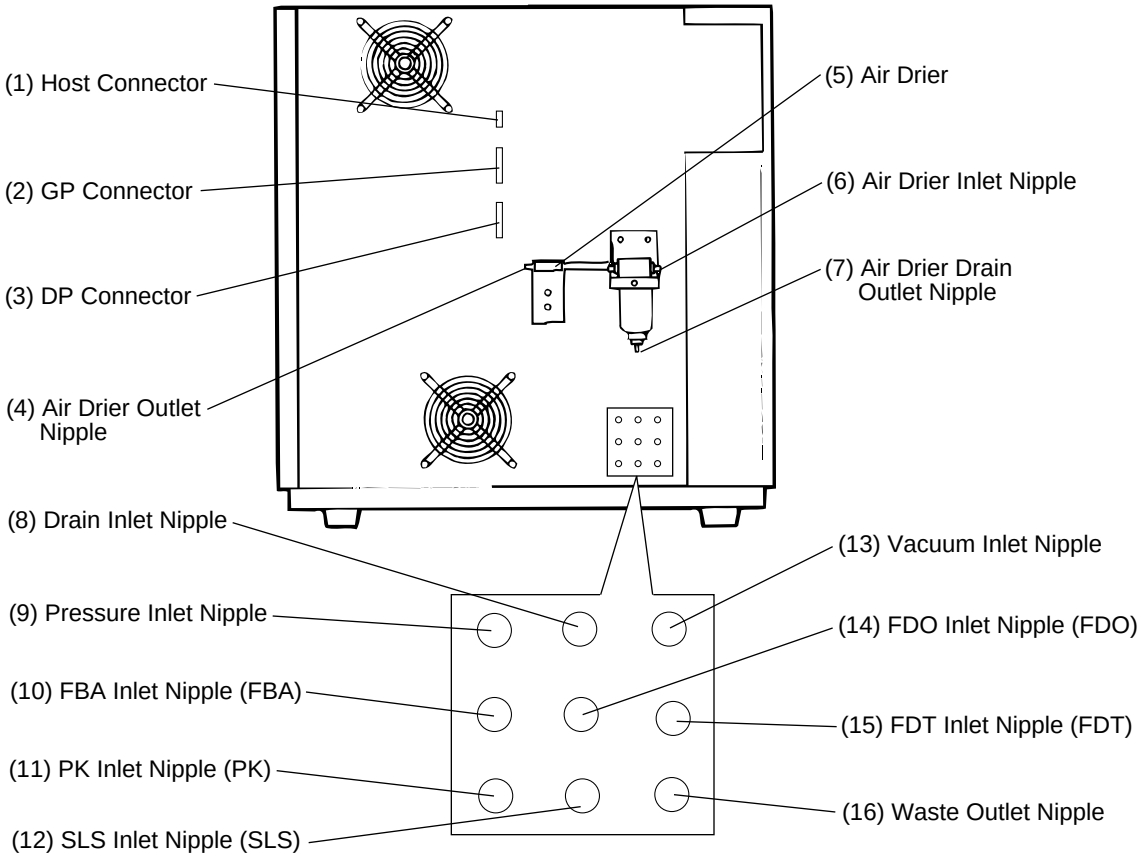

(1) Host Connector
(2) GP Connector
(3) DP Connector
(4) Air Drier Outlet Nipple
(5) Air Drier
(6) Air Drier Inlet Nipple
(7) Air Drier Drain Outlet Nipple
(8) Drain Inlet Nipple
(9) Pressure Inlet Nipple
(10) FBA Inlet Nipple (FBA)
(11) PK Inlet Nipple (PK)
(12) SLS Inlet Nipple (SLS)
(13) Vacuum Inlet Nipple
(14) FDO Inlet Nipple (FDO)
(15) FDT Inlet Nipple (FDT)
(16) Waste Outlet Nipple

Figure 10-18: Main Unit – Rear View

(1) Host Connector
Used for communication with the host computer.

(2) GP Connector
Used as the output connector for the graphic printer.

(3) DP Connector
Used as the output connector for the data printer.

(4) Air Drier Outlet Nipple
Connects to the pressure nipple on the Main Unit.

(5) Air Drier
Removes dust and moisture from the (pressure side) air supplied by the Pneumatic Unit.

(6) Air Drier Inlet Nipple
Connects to the pressure nipple on the Pneumatic Unit.

(7) Air Drier Drain Outlet Nipple
Connects to the drain inlet nipple on the Main Unit.

(8) Drain Inlet Nipple
Connects to the air drier drain outlet nipple. The accumulated fluid in the air drier is drained via this nipple to the waste line inside the Main Unit.

(9) Pressure Inlet Nipple
Connects with the air drier outlet nipple.

(10) FBA Inlet Nipple (FBA)
BASO reagent (STROMATOLYSER-FB) is aspirated through this nipple. Connects with the BASO reagent container.

(11) PK Inlet Nipple (PK)
Diluent (CELLPACK) is aspirated through this nipple. Connects with the diluent container.

(12) SLS Inlet Nipple (SLS)
HGB reagent (SULFOLYSER) is aspirated through this nipple. Connects with the HGB reagent container.

(13) Vacuum Inlet Nipple
Connects with the vacuum outlet nipple on the Pneumatic Unit.

(14) FDO Inlet Nipple (FDO)
WBC reagent (STROMATOLYSER-FD (I)) is aspirated through this nipple. Connects with the STROMATOLYSER-FD (I) container.

(15) FDT Inlet Nipple (FDT)
WBC reagent (STROMATOLYSER-FD (II)) is aspirated through this nipple. Connects with the STROMATOLYSER-FD (II) container.

(16) Waste Outlet Nipple
Waste fluid discharges from this nipple. Can be connected to a sewer system or a waste container.

9.3 Right Side

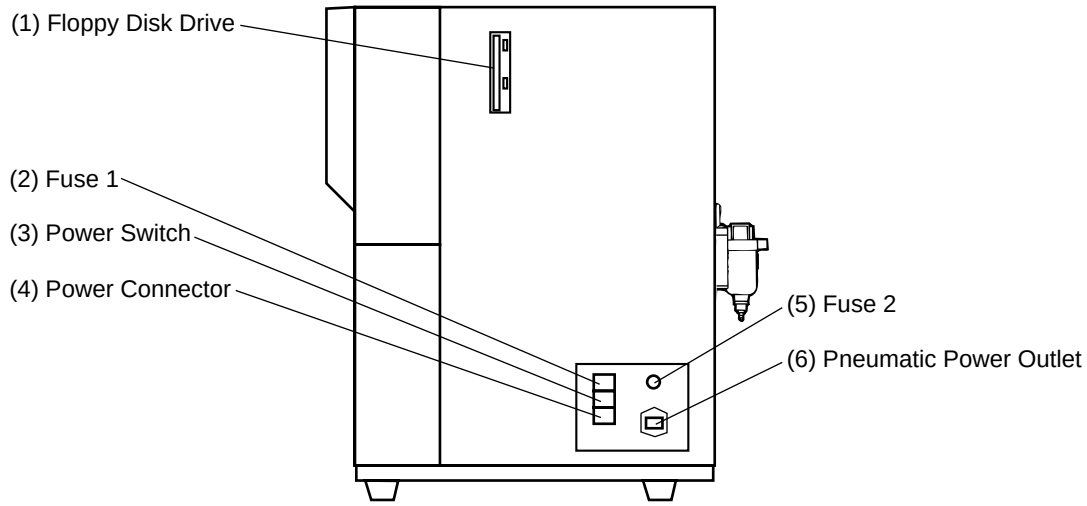


Figure 10-19: Main Unit – Right Side View

(1) 3.5-Inch Floppy Disk Drive

Uses 3.5 inch 2HD (double sided high density) type floppy disks.

> **CAUTION:** The floppy disks for the SF-3000 can be used only on this instrument. If the disks are used on other instruments or computers, the data may be unreadable on the SF-3000.

(2) Fuse 1

This is an over-current protection fuse for SF-3000 including the Pneumatic Unit. Replace with provided time lag type fuse. The rating will be different depending on the instrument specification.

Specification	Part No.	Description	Fuse Type
117 VAC	266-5108-7	Fuse 250V8A ST4-8A-N1	Time Lag
220/240 VAC	266-5297-4	Fuse 250V4A No. 19195	Time Lag

(3) Power Switch

Turns the Main Unit power ON and OFF.

> **CAUTION:** Do not turn it ON and OFF repeatedly in a short period of time.

(4) Power Connector
Supplies power via power cord provided.

(5) Fuse 2
This is an over-current protection fuse for the Pneumatic power outlet. Replace with provided time lag type fuse. The rating will be different depending on the instrument specification.

Specification	Part No.	Description	Fuse Type
117 VAC	266-5106-0	Fuse 250V6.3A ST4-6.3A-N1	Time Lag
220/240 VAC	266-5293-0	Fuse 250V3.15A No. 19195	Time Lag

(6) Pneumatic Power Outlet
Supplies power to the Pneumatic Unit. When the Pneumatic Unit is not operated for preset time period, the Main Unit automatically powers off the Pneumatic Unit.

9.4 Left Side

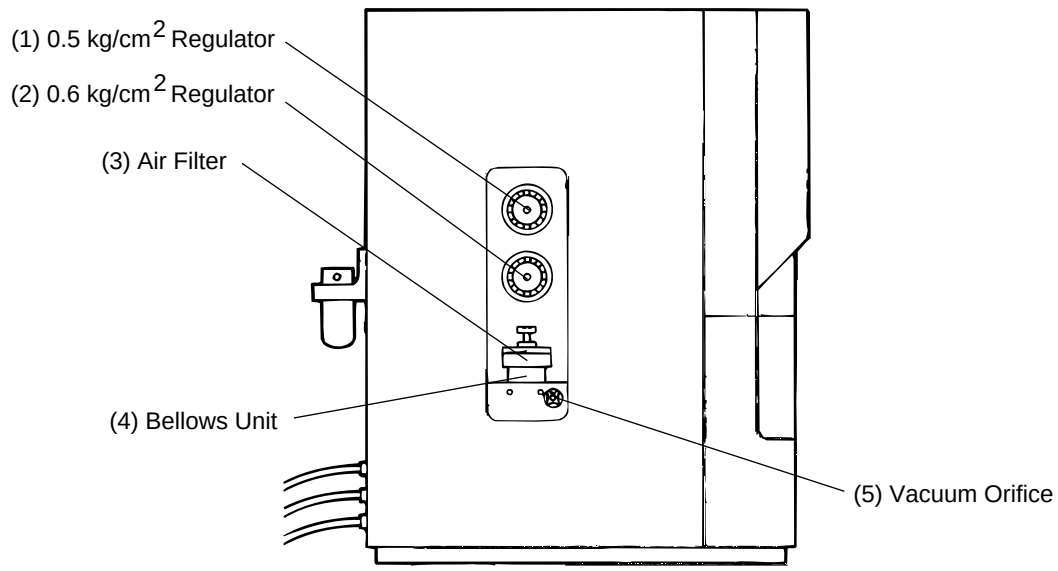


Figure 10-20: Main Unit – Left Side View

(1) 0.5 kg/cm^2 Regulator
Adjusts the pressure to 0.5 kg/cm^2.

(2) 0.6 kg/cm^2 Regulator
Adjusts the pressure to 0.6 kg/cm^2.

(3) Air Filter
Prevents dust from entering into the bellows unit.

(4) Bellows Unit
Adjusts vacuum to 250 mmHg.

(5) Vacuum Orifice
Adjusts the vacuum (250 mmHg) supplied to the waste chamber.

9.5 Front Interior

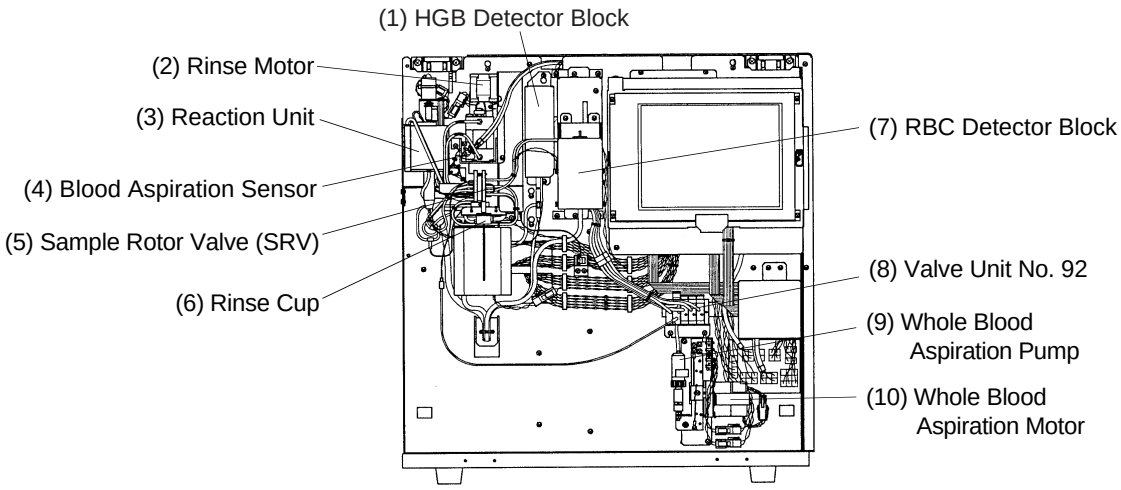

(1) HGB Detector Block
(2) Rinse Motor
(3) Reaction Unit
(4) Blood Aspiration Sensor
(5) Sample Rotor Valve (SRV)
(6) Rinse Cup
(7) RBC Detector Block
(8) Valve Unit No. 92
(9) Whole Blood Aspiration Pump
(10) Whole Blood Aspiration Motor

Figure 10-21: Main Unit – Front Interior

(1) HGB Detector Block
Contains HGB detector unit.

(2) Rinse Motor
Drives the Manual Rinse Mechanism.

(3) Reaction Unit
WBC reagents are added to WBC samples, temperature-controlled. Then, the sample is sent to the WBC detector for analysis.

(4) Blood Aspiration Sensor
Monitors whole blood aspiration when using the sampler and manual closed modes.

(5) Sample Rotor Valve (SRV)
Aliquots the aspirated whole blood sample.

(6) Rinse Cup
Rinses and wipes the manual pipette every operation cycle to eliminate the carryover from the previous sample.

(7) RBC Detector Block
Contains RBC detector.

(8) Valve Unit No. 92 Assembly
Controls the fluid flow. This assembly includes Solenoid Valves SV1 through SV4, and Master Valve MV1.

(9) Whole Blood Aspiration Pump
Aspirates the whole blood sample.

(10) Whole Blood Aspiration Motor
Drives the whole blood aspiration pump.

9.6 Left Interior

WARNING! Do not open the Left Side Cover without assistance of Sysmex service representative.

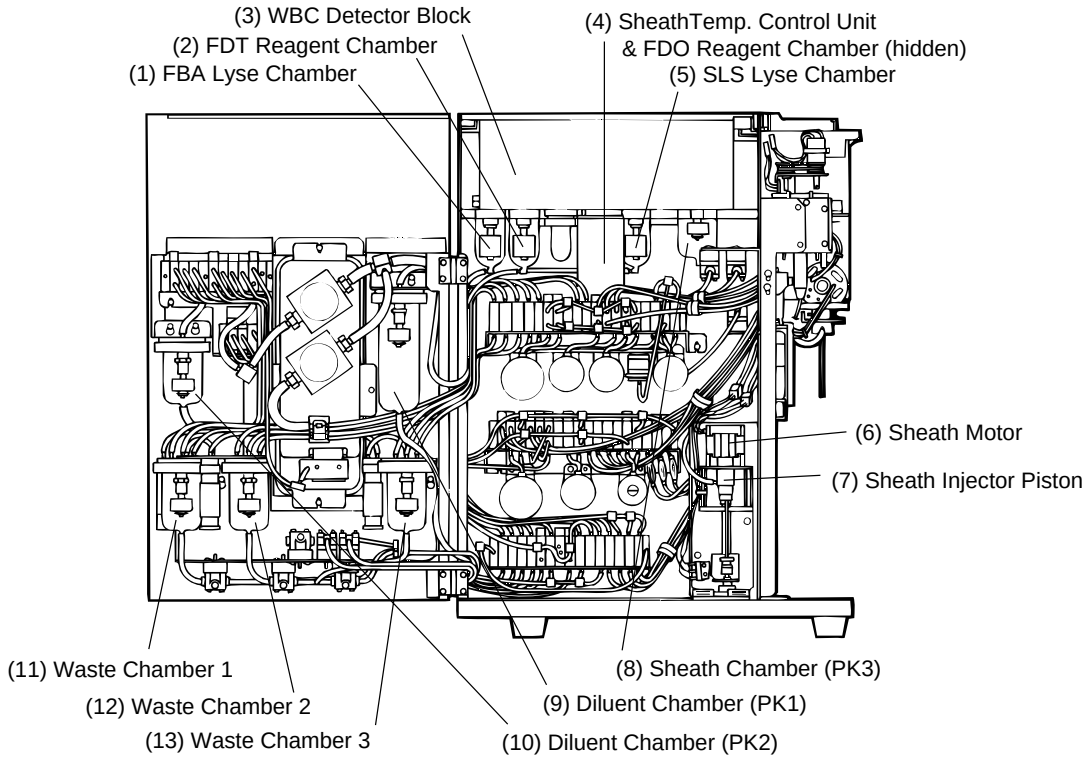

(3) WBC Detector Block
(2) FDT Reagent Chamber
(1) FBA Lyse Chamber
(4) SheathTemp. Control Unit
& FDO Reagent Chamber (hidden)
(5) SLS Lyse Chamber
(6) Sheath Motor
(7) Sheath Injector Piston
(11) Waste Chamber 1
(12) Waste Chamber 2
(13) Waste Chamber 3
(8) Sheath Chamber (PK3)
(9) Diluent Chamber (PK1)
(10) Diluent Chamber (PK2)

Figure 10-22: Main Unit – Left Interior (Chambers)

(1) FBA Lyse Chamber
Reservoir chamber for the WBC/BASO reagent [STROMATOLYSER-FB].

(2) FDT Reagent Chamber
Reservoir chamber for the WBC reagent [STROMATOLYSER-FD (II)].

(3) WBC Detector Block
Contains WBC detector unit.

WARNING! Never open the WBC Detector Block cover. Up to 2 mW of laser light is accessible inside this unit and beam can damage your eyes.

(4) Sheath Temperature Control Unit
Controls the sheath fluid temperature.

(4') FDO Reagent Chamber (located back of the "Sheath Temp. Control Unit")
Reservoir chamber for the WBC reagent [STROMATOLYSER-FD (I)].

(5) SLS Lyse Chamber
Reservoir chamber for the HGB reagent [SULFOLYSER].

(6) Sheath Motor
Drives the sheath injector piston.

(7) Sheath Injector Piston
Supplies a preset volume of diluted WBC sample with WBC reagents to the WBC detector.

(8) Sheath Chamber (PK3)
Reservoir chamber for the diluent [CELLPACK] that is supplied to the Sheath Temp. Control Unit.

(9) Diluent Chamber (PK1)
Reservoir chamber for the diluent [CELLPACK] that is supplied to the RBC Manometer, RBC Dilution DP, Hgb Dilution DP, Dilution Sample Asp./Rinse DP, Whole Blood Aspiration Pump, and SRV Perimeter cleaning.

(10) Diluent Chamber (PK2)
Reservoir chamber for the diluent [CELLPACK] that is supplied to the Reaction Chamber rinse, and the Sheath Syringe priming.

(11) Waste Chamber 1
Accumulates waste from the Mixing Chamber, RBC Td Chamber, RBC Manometer line, Hgb Flow Cell, SRV perimeter cleaning, manual Rinse Cup, and Piercer Rinse Cup in the CP Sampler Unit.

(12) Waste Chamber 2
Accumulates waste from Reaction Unit, Sheath Charging line, and Sheath Temp. Control Unit.

(13) Waste Chamber 3
Accumulates waste from the Sheath Flow Cell.

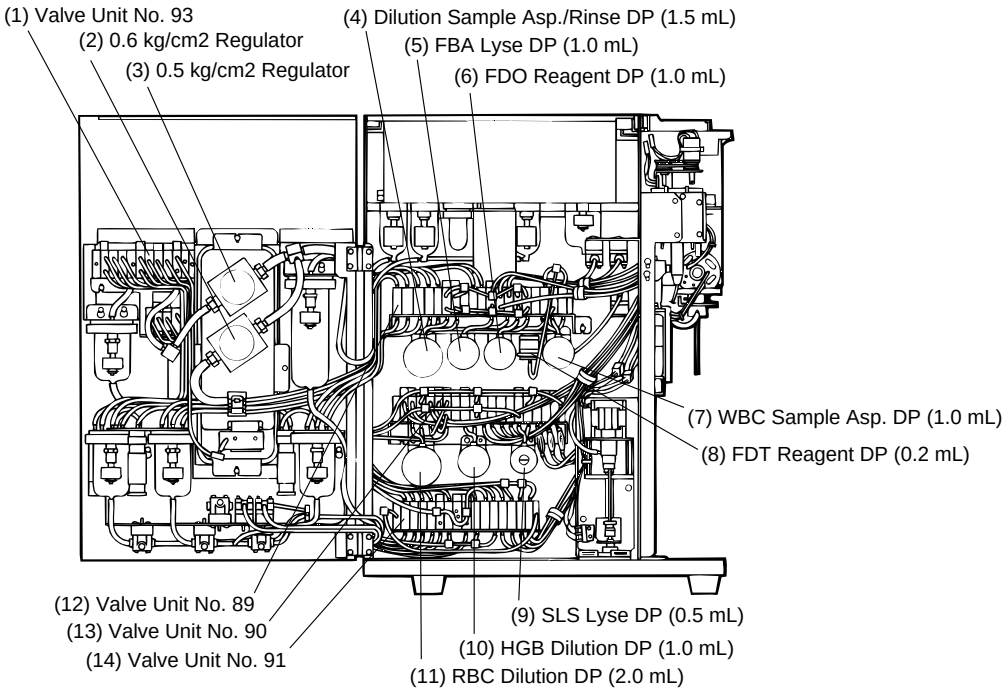

(1) Valve Unit No. 93
(2) 0.6 kg/cm2 Regulator
(3) 0.5 kg/cm2 Regulator
(4) Dilution Sample Asp./Rinse DP (1.5 mL)
(5) FBA Lyse DP (1.0 mL)
(6) FDO Reagent DP (1.0 mL)
(7) WBC Sample Asp. DP (1.0 mL)
(8) FDT Reagent DP (0.2 mL)
(9) SLS Lyse DP (0.5 mL)
(10) HGB Dilution DP (1.0 mL)
(11) RBC Dilution DP (2.0 mL)
(12) Valve Unit No. 89
(13) Valve Unit No. 90
(14) Valve Unit No. 91

Figure 10-23: Main Unit – Left Interior (Diaphragm Pumps)

(1) Valve Unit No. 93 Assembly
Controls the fluid flow. This assembly includes Solenoid Valves SV46 through SV53, and Master Valves MV47 through MV54.

(2) 0.6 kg/cm^2 Regulator
Adjusts the pressure to 0.6 kg/cm^2.

(3) 0.5 kg/cm^2 Regulator
Adjusts the pressure to 0.5 kg/cm^2.

(4) Dilution Sample Asp./Rinse DP (1.5 mL)
Aspirates RBC dilution sample from the Mixing Chamber through the SRV, and also supplies diluent to the Rinse Cup for cleaning.

(5) FBA Lyse DP (1.0 mL)
Dispenses aliquot of STROMATOLYSER-FB into the WBC/BASO dilution sample in the Reaction Chamber.

(6) FDO Reagent DP (1.0 mL)
Dispenses aliquot of STROMATOLYSER-FD(I) into the 4DIFF dilution sample in the Reaction Chamber.

(7) WBC Sample Asp. DP (1.0 mL)
Aspirates WBC/BASO dilution sample and 4DIFF dilution sample to the sheath charging line from the Reaction Chamber.

(8) FDT Reagent DP (0.2 mL)
Dispenses aliquot of STROMATOLYSER-FD(II) into the 4DIFF dilution sample in the Reaction Chamber.

(9) SLS Lyse DP (0.5 mL)
Dispenses aliquot of SULFOLYSER into the HGB dilution sample in the HGB Flow Cell.

(10) HGB Dilution DP (1.0 mL)
Dispenses 3 µL of the whole blood along with 1 mL of the diluent into the HGB Flow Cell through the SRV, and also dispenses the diluent to the HGB Flow Cell for rinsing.

(11) RBC Dilution DP (2.0 mL)
Dispenses 4 µL of the whole blood along with 2 mL of the diluent into the Mixing Chamber through the SRV, and also dispenses 40 µL of the 1:500 dilution sample along with 2 mL of the diluent to the RBC Transducer Chamber through the SRV.

(12) Valve Unit No. 89 Assembly
Controls the fluid flow. This assembly includes Solenoid Valves SV5 through SV18, and Master Valves MV2 through MV18.

(13) Valve Unit No. 90 Assembly
Controls the fluid flow. This assembly includes Solenoid Valves SV19 through SV33, and Master Valves MV19 through MV32.

(14) Valve Unit No. 91 Assembly
Controls the fluid flow. This assembly includes Solenoid Valves SV34 through SV45, and Master Valves MV33 through MV46.

9.7 Right Interior

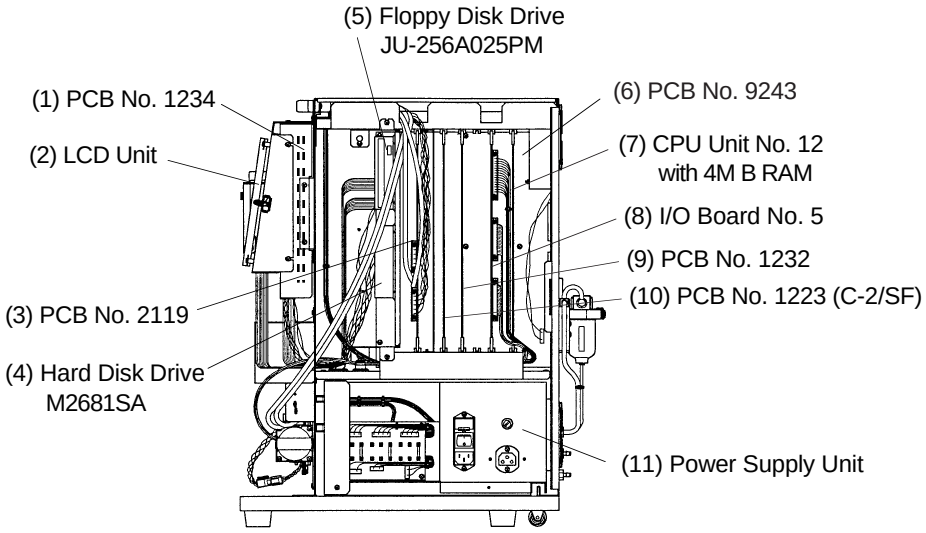


Figure 10-24: Main Unit – Right Interior

(1) PCB No. 1234 Complete Assy
This driver board receives heater-related thermistor data and controls heaters, motors, and solenoid valves.

(2) SF-3000 LCD Unit
Consists of an LCD KCL6448HSTT-X14, an Inverter KCL-T1, a Touch Panel H94-51, and PCB No. 9245.

(3) PCB No. 2119 Complete Assy
An analog main board. All the cell signals and sample temperature obtained in the 4DIFF, WBC/BASO, RBC and HGB Detectors come in this board.

(4) Hard Disk Drive M2681SA
Stores program, setting data, analyzed patient data, and QC data.

(5) Floppy Disk Drive JU-256A025P
Writes and reads data to and from a pre-formatted floppy disk.

(6) PCB No. 9243
This is a mother board.

(7) CPU Unit No. 12
This CPU board and extended memory board control the entire SF-3000 electric system.

(8) I/O Board No. 5 Assy
This I/O board has following interfaces and functions; a keyboard interface, printer interface, serial I/O interface, AGDC (Advanced Graphic Display Controller), SCSI (Small Computer System Interface), DMA (Direct Memory Access), FDC (Floppy Disk Controller), and Bus Interface.

(9) PCB No. 1232
This board includes a WBC scattergram analysis function, stepper motor control, and serial interface I/O to and from the Sampler and ID reader.

(10) PCB No. 1223
This is an RBC PDA board.

(11) SF-3000 Power Supply Unit
Supplies required voltages and current to each unit.

NOTE: Parts information for ordering is given below.

	Part Code No.	Part Description
<PCB No. 2119>	943-2391-0	PCB No. 2119
<LCD Unit>	228-3700-6	LCD KCL6448HSTT-X14
	228-9350-2	Inverter KCL-T1
	263-9175-0	Touch Panel H94-51
	943-2441-9	PCB No. 9245
<PCB No. 1234>	943-2361-8	PCB No. 1234
<HD Drive>	241-9412-6	Hard Disk Unit M2681SA
<FD Drive>	241-9325-9	Floppy Disk Drive JU-256A025P
<PCB No. 9243>	943-2431-1	PCB No. 9243
< CPU Unit >	943-2411-7	PCB No. 6358
	943-2421-4	PCB No. 7013 (C-1/4MB)
	943-2461-3	ROM 2SF31 Assy
<I/O Board>	943-2321-9	PCB No. 122901 with ROM 3SF31
	943-2471-1	ROM 3SF31 Assy
	943-2331-6	PCB No. 1230
<PCB No. 1232>	943-2341-3	PCB No. 1232
<PCB No. 1223>	933-3952-5	PCB No. 1223 with ROM (C2/SF)

10. PNEUMATIC UNIT COMPONENTS

10.1 Front

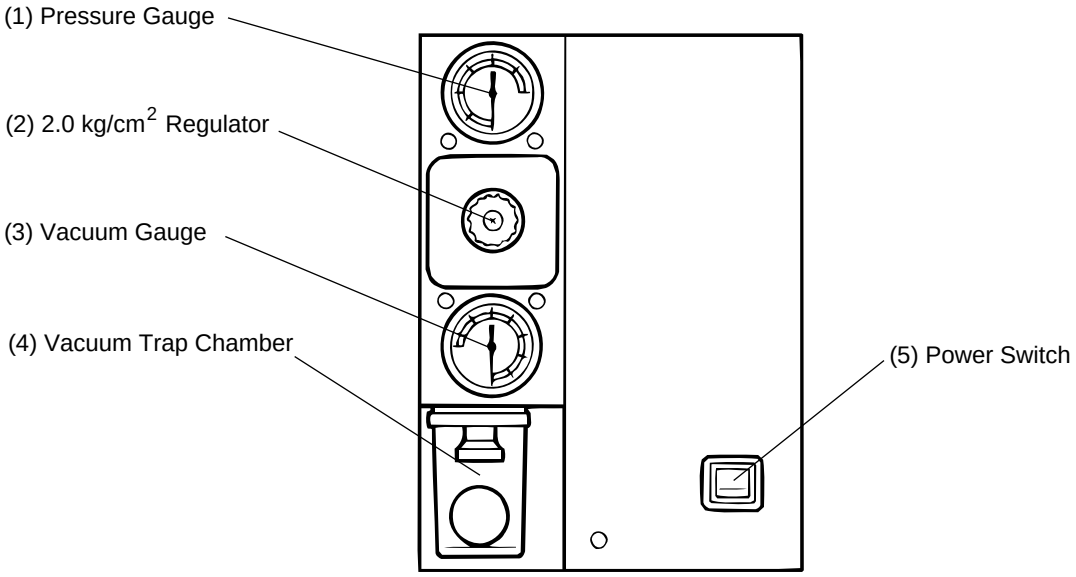


Figure 10-25: Pneumatic Unit – Front View

(1) Pressure Gauge (2.0 kg/cm^2)
Indicates the pressure supplied to the Main Unit (normally 1.8 kg/cm^2 or higher). The instrument will not operate properly if the pressure is not within the normal range.

(2) 2.0 kg/cm^2 Regulator
Adjusts the pressure to 2.0 kg/cm^2.

(3) Vacuum Gauge (Vacuum)
Indicates the vacuum supplied to the Main Unit (normally 400 mmHg). The instrument will not operate properly if the vacuum is less than 400 mmHg.

(4) Vacuum Trap Chamber
Prevents fluid from flowing into the compressor during an instrument failure. Make sure that the ball float is inside.

(5) Power Switch
Turns the Pneumatic Unit power ON and OFF.

> **CAUTION:** Do not turn it ON and OFF repeatedly in a short period of time.

10.2 Right Side

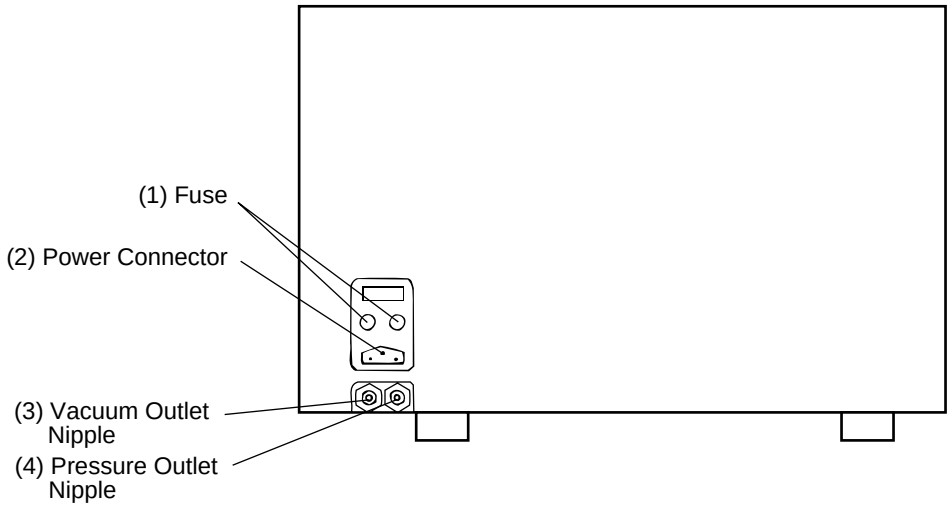


Figure 10-26: Pneumatic Unit – Right Side View

(1) Fuse
Replace with provided time lag type fuse. The rating will be different depending on the instrument specification.

Specification	Part No.	Description	Fuse Type
117 VAC	266-5011-3	Fuse 250V4A ST4-4A-N1	Time Lag
220/240 VAC	266-5292-6	Fuse 250V2A No. 19195	Time Lag

(2) Power Connector
Connects with the Pneumatic Power Outlet on the Main Unit right side panel.

(3) Vacuum Outlet Nipple
Vacuum is supplied to the Main Unit through this nipple. Connects with the vacuum inlet nipple on the Main Unit.

(4) Pressure Outlet Nipple
Pressure is supplied to the Main Unit through this nipple. Connects with the pressure inlet nipple on the air drier on the rear panel of the Main Unit.

10.3 Top Interior

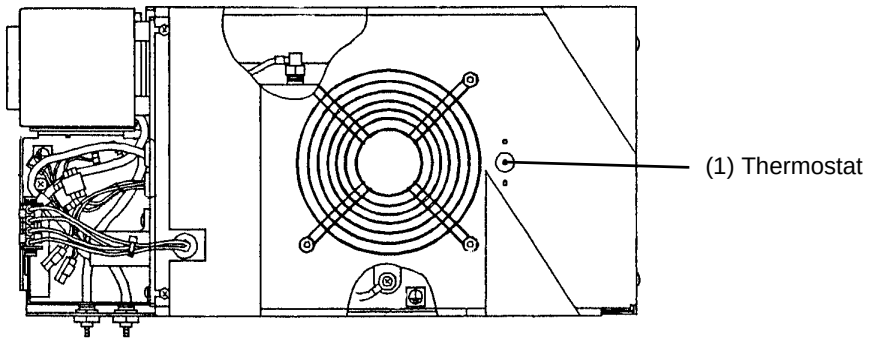


Figure 10-28: Pneumatic Unit – Top Interior

(1) Thermostat
Senses the temperature of the compressor. Compressor power is automatically cut off when excessive temperature is detected.

10.4 Right Interior

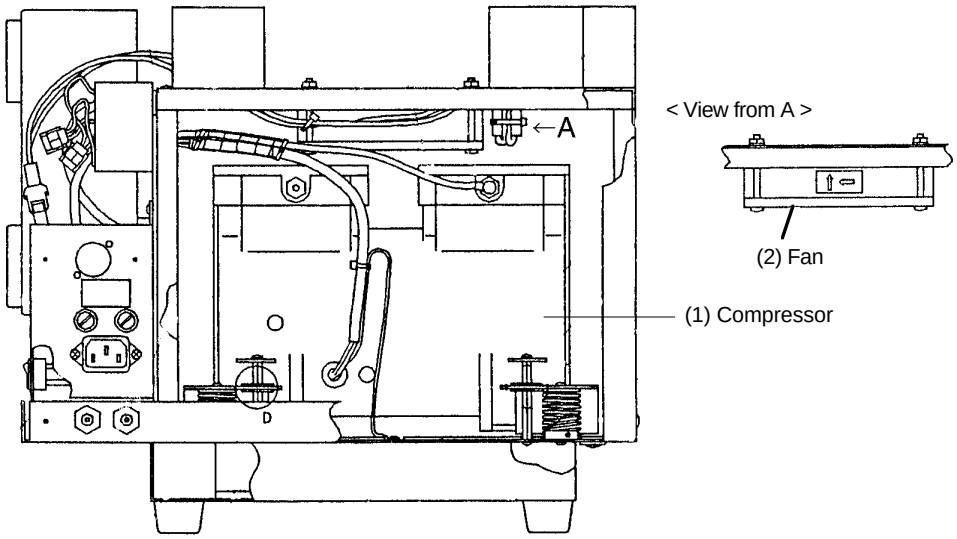


Figure 10-29: Pneumatic Unit – Right Interior

(1) Compressor
Generates both pressure and vacuum for the system.

(2) Fan
Exhausts heat generated in the Pneumatic Unit.

11. CAP PIERCING SAMPLER UNIT (OPTION)

11.1 Top

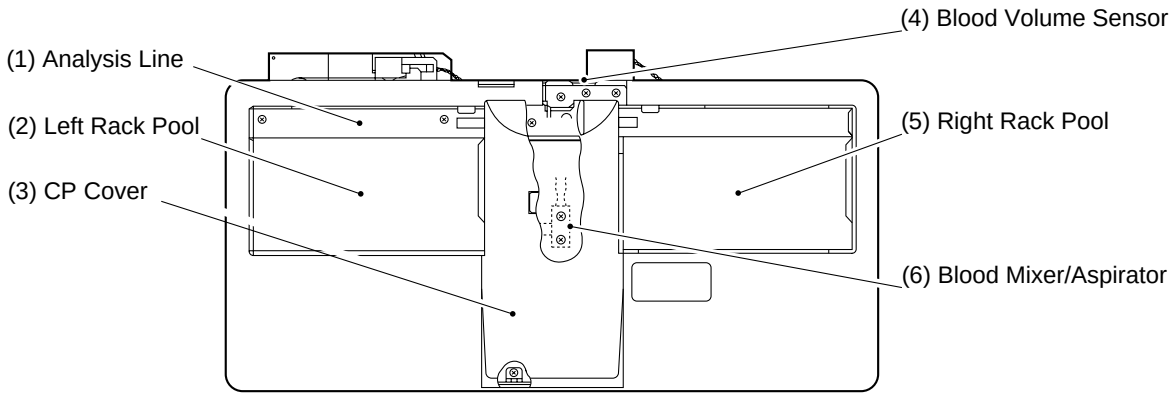


Figure 10-30: CP Sampler Unit

(1) Analysis Line
A rack is automatically shifted to the left once per cycle. The ID label is read and the sample collection tube is delivered to the Cap Piercing Unit.

(2) Left Rack Pool
Racks are sent to this pool from the analysis line.

(3) CP Cover
Protection cover on the Cap Piercing Unit. Can be removed manually.

> **WARNING!** Do not remove this cover during sampler unit operation.

(4) Blood Volume Sensor
Monitors the volume of blood in the collection tube. If the blood volume is low, the sample is not analyzed.

(5) Right Rack Pool
Up to 5 racks can be set at a time in this pool. When the Sampler Start switch is pressed, the rack will be forwarded to the analysis line.

(6) Blood Mixer/Aspirator
Inverts a sample ten times for mixing; then aspirates the blood via the Cap Piercing Unit.

11.2 Top Interior

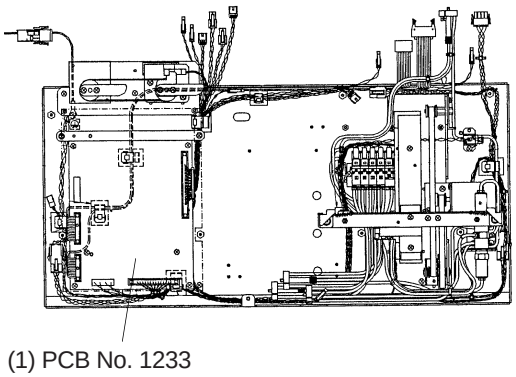


Figure 10-31: CP Sampler Unit - Top Interior

(1) PCB No. 1233
Controls the solenoid valves, sensors and stepping motors in the Sampler Unit.

NOTE: Parts information for ordering is given below.

Part Code No.	Part Description
943-2351-1	PCB No. 1233
943-2481-8	ROM 4SF31 Assy

12 MANUAL CP UNIT (OPTION)

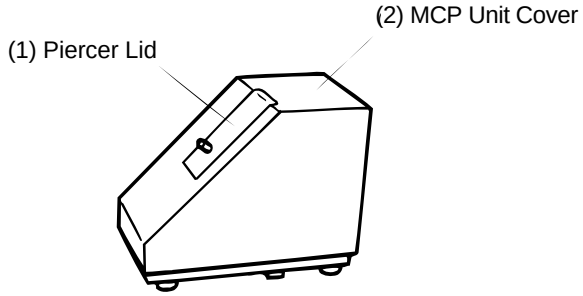


Figure 10-32: Manual CP Unit

(1) Piercer Lid
Open to set a collection tube after mixing.

(2) MCP Unit Cover
Can be removed by pulling it straight up.

> **WARNING!** Do not remove this cover while the MCP unit is operating.

13. REAGENT SYSTEM

The reagent system consists of three types of reagents: (1) Diluent, (2) Lyse Reagents, and (3) Detergent. Refer to Table 10-1 on the next page for further information.

Diluent:	CELLPACK	Used to dilute whole blood specimens to determine hemoglobin, to count and size the red blood cells and platelets, and determine hematocrit. Also, this reagent forms a laminar sheath flow around the diluted specimen through WBC flow cell where white blood cell counting and sizing take place.
Lyse:	STROMATOLYSER-FD (I)	Used in combination with STROMATOLYSER-FD (II) to eliminate red blood cell stroma for accurate counting and sizing of the Lymphocytes, Monocytes, Eosinophils, and the group of Neutrophils and Basophils.
	STROMATOLYSER-FD (II)	Used in combination with STROMATOLYSER-FD (I) to eliminate red blood cell stroma for accurate counting and sizing of the Lymphocytes, Monocytes, Eosinophils, and the group of Neutrophils and Basophils.
	STROMATOLYSER-FB	Lyses red blood cells and eliminates white blood cell stroma other than Basophils to count and size Basophils, and to determine WBC total count. The denucleated white blood cells will be shrunken to be smaller than other blood cells.
	SULFOLYSER	Lyses red blood cells and releases hemoglobin for measurement by the SLS-Hemoglobin Method.
Detergent:	CELLCLEAN	Strong alkaline detergent which removes lyse reagents, cellular residuals, and blood proteins remaining in the hydraulics.

Table 10-1: Reagent Information

Reagent	Storage	If Frozen...	Open Shelf Life (Use within...)	WARNING!!!
CELLPACK	15 - 30°C	Thaw & mix thoroughly before use.	60 days	None
STROMATOLYSER-FD (I)	5 - 30°C	REPLACE!	60 days	None
STROMATOLYSER-FD (II)	5 - 30°C	REPLACE!	60 days	None
STROMATOLYSER-FB	2 - 30°C	Thaw & mix thoroughly before use.	60 days	None
SULFOLYSER	15 - 30°C	Dissolve precipitate by warming reagent in water bath at 30°C with occasional mixing.	60 days	None
CELLCLEAN	15 - 30°C	REPLACE!	*8 months after manufacturing	Strong alkaline detergent. Avoid contact with skin, eyes, clothing.

NOTE:
- Product life unopened after manufacturing is 12-18 months.
- Avoid direct sunlight during storage and use.
- If reagent displays any signs of contamination, cloudiness, instability or color change, replace it.

CHAPTER 11 SYSTEM SETUP

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1. INTRODUCTION

System setup of the SF-3000 will be performed by the Sysmex Service Representative when the instrument is installed. However, the settings can be changed according to each laboratory's needs by using the Setting Programs explained in this chapter. This chapter consists of the following sections.

Auto Management

Explains setting conditions for the initiation of Auto Output (which will direct automatic data transmission and/or printout), Auto Erase (which allows automatic data erasing when the memory is full), and Auto Validation (which validates the previously specified data allowing automatic output of results).

Data Criteria

Explains setting upper and lower limits for abnormal patient data (marking of abnormal data with flags).

- **Mark Limits**
  Explains setting upper and lower limit ranges for abnormal patient data.
- **Critical Limits**
  Explains setting upper and lower limits for critical data.
- **Sampler Stop Limits**
  Explains setting upper and lower limits for stopping the sampler's operation.
- **Sampler Stop Conditions**
  Explains setting the various conditions for stopping the sampler's operation.

Flag System

Explains setting criteria for flagging of WBC, RBC and PLT abnormal IP messages.

Output Condition

Explains setting of printer output conditions, print formats and interface conditions for transmission of data to each type of peripheral device.

General Set Up

Explains setting of SF-3000 system status:

- **Date/Time**
  Sets the date and time on the SF-3000 built-in clock.
- **Units**
  Sets the analysis units to be used for the display screen and printouts.
- **Timer Mode**
  Activates or deactivates the timer used to shut off the pneumatic power. (The timer automatically switches off the power to the Pneumatic Unit if the Main Unit has not been operated within a set time.)
- **Normal Range**
  Sets the overlay of a (normogram) normal range to be printed on cell size distributions.
- **Date Format**
  Sets the format of the date display and printouts.
- **ID Reader**
  Enables the ID Reader and sets the type of labels and check digits used.
- **Blood Sensor**
  Sets the use of the blood aspiration sensor.
- **Work List**
  Sets the use of the work list and the keyword for order inquiry.

Print Set Values

Prints out a list of the settings.

Backup Set Values

Copies setting data to a floppy disk.

2. AUTO MANAGEMENT PROGRAMS

Use this program to set the following conditions.

- Output Conditions, which will direct automatic data transmission and/or printout.
- Output Mode, which will specify the type of samples.
- Auto Erase program, which automatically erases the oldest data if the memory is full when new data is stored.
- Auto Validation, which automatically validates the previously specified data to output to the peripheral devices.

Three different output devices can be connected:

- DP (Data Printer)
- GP (Graphic Printer)
- HC (Host Computer)

NOTE:
- Only the sample data which is accepted by auto validation program will be output to the peripheral devices.
- Once sample data has been output to an output device, it will not be output to the same device or be validated automatically.

To execute auto management programs:

(1) Press the [Settings] key in the root menu. The settings second menu will be displayed.

NOTE: If the [Settings] keypad is not displayed on the LCD, press [More] key to change the displayed root menu.

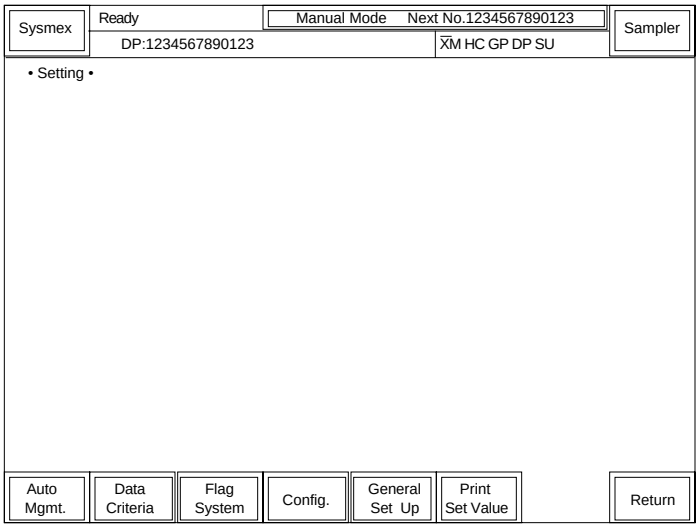


Figure 11-1: Settings Second Menu Screen

(2) Press [Auto Mgmt.] key in the second menu. The Auto Management submenu appears as shown in Figure 11-2.

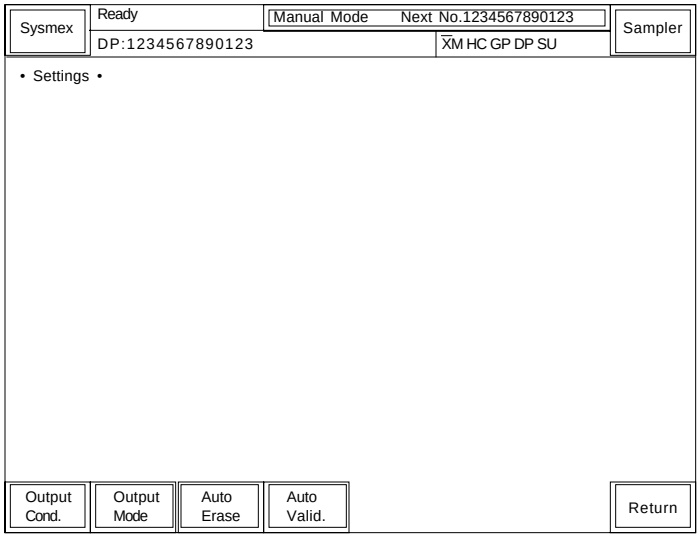


Figure 11-2: Auto Management Submenu Screen

(3) Press a desired keypad to execute the program.
When [Output Mode], [Auto Erase] or [Auto Valid.] key is pressed, the Input Password window will appear. Input the registered password and press [ENTER].

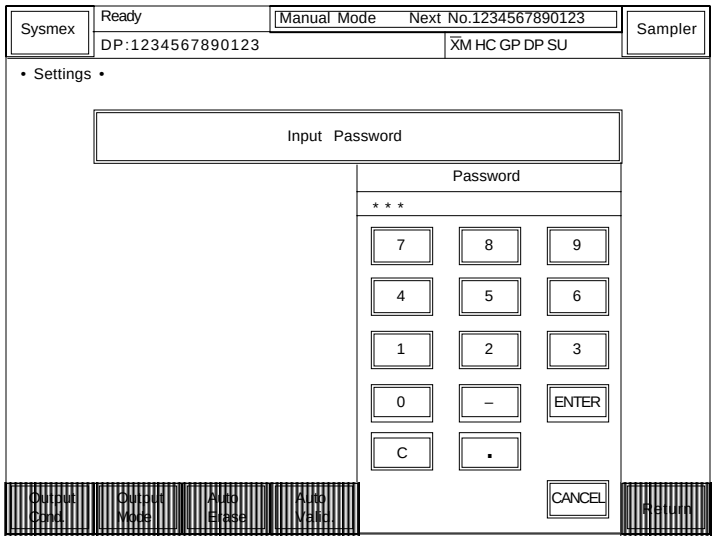


Figure 11-3: Password Input Window

(4) Proceed each program by referring to the following sections.

(5) When [Quit] key is pressed to exit the setting program, the confirmation message window will appear. Press the appropriate key [Continue], [Set] or [Cancel].

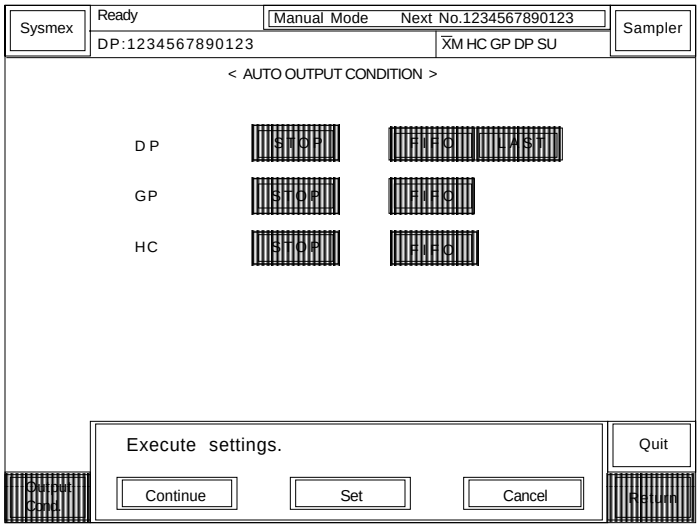


Figure 11-4: Example of End of Setting Window

Continue : To return to the previous screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

2.1 Auto Output Condition

Use this program to specify auto output conditions for DP, GP/LP and HC.

To specify auto output conditions:

(1) Press [Output Cond.] key in the Auto Management submenu.
The current output conditions will appear on the Auto Output Conditions setting screen. The keypads of the currently selected item are backlit in light-blue.

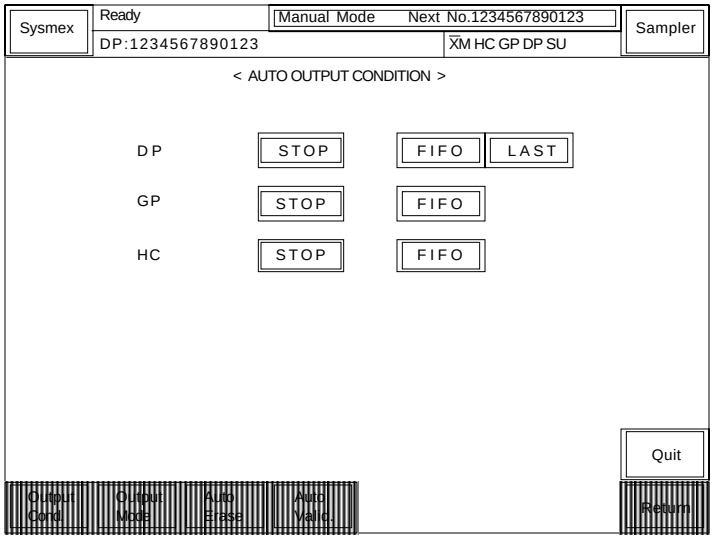


Figure 11-5: Auto Output Condition Setting Window

(2) Press the appropriate key to select the condition. The condition selected will be backlit in light-blue.

> **NOTE:** The factory setting is "FIFO" for all devices.

The available conditions are listed in Table 11-1.

Table 11-1: Auto Output Available Conditions

DP (Data Printer)	STOP	Automatic printing to Data Printer will not be performed.
	FIFO (First-in, first-out)	The stored data not yet printed out on the Data Printer will be automatically printed out in the order of analysis.
	LAST (Last Data)	Analysis data only for the latest sample (currently displayed on the processing screen) will be printed out automatically.
GP (Graphic Printer)	STOP	Automatic printing to Graphic Printer is not performed.
	FIFO (First-in, first-out)	The stored data not yet printed by the Graphic Printer will be automatically printed out in the order of analysis.
HC (Host Computer)	STOP	Automatic data output to the Host Computer will not be performed.
	FIFO (First-in, first-out)	Stored data not yet transmitted to the Host Computer will be automatically transmitted in the order of analysis.

NOTE: Automatic data transmission to HC will be stopped if any communication error occurs. In such cases, check interface conditions, and reset "HC Auto Output" condition. Refer to *Chapter 8: Troubleshooting.*

(3) Press [Quit] key to exit the program. The confirmation message window will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue : To return to Auto Output Condition setting screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

2.2 Auto Output Mode (Data Specification)

Use this program to specify the type of samples for auto output to the DP, GP and/or HC.

To specify auto output data:

(1) Press [Output Mode] key in the Auto Management submenu.

(2) Enter the password and press [ENTER] key.
The Output Mode setting screen, containing the current output settings, will appear. The conditions selected will be marked by a check mark (√).

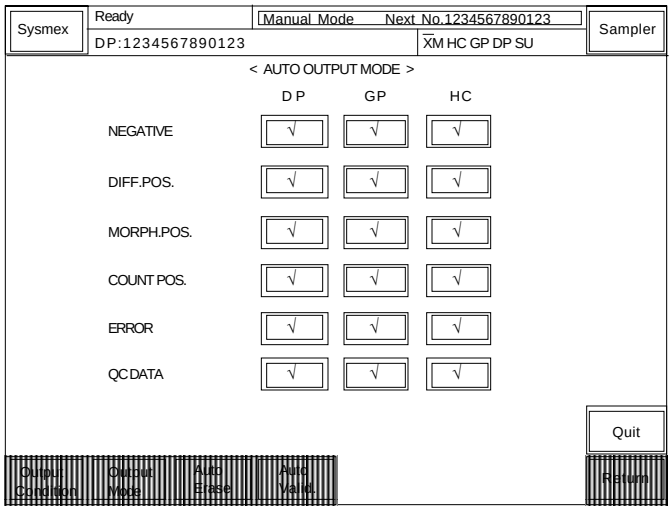


Figure 11-6: Output Mode Setting Window

(3) Press the appropriate key to select the output data. To disable the setting for the options, press the keys marked "√".

The data output selections are as follows:

NEGATIVE	:	outputs sample data without analysis errors or IP messages.
DIFF. POS.	:	outputs sample data with differential IP message.
MORPH. POS.	:	outputs sample data with cell morphology IP message.
COUNT POS.	:	outputs sample data with cell count IP message.
ERROR	:	outputs sample data with analysis error.
QC DATA	:	outputs data of QC Sample.

> **NOTE:** The factory setting is "√" for all items.

(4) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Output Mode setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

2.3 Auto Erase

Use this program to start or stop the automatic erasing of the oldest data if the memory is full when new data is stored.

To set auto erase:

(1) Press [Auto Erase] key in the Auto Management submenu.

(2) Enter the password and press [ENTER] key.
The current auto erase condition will appear on the Auto Erase setting screen. The condition selected is backlit in light-blue.

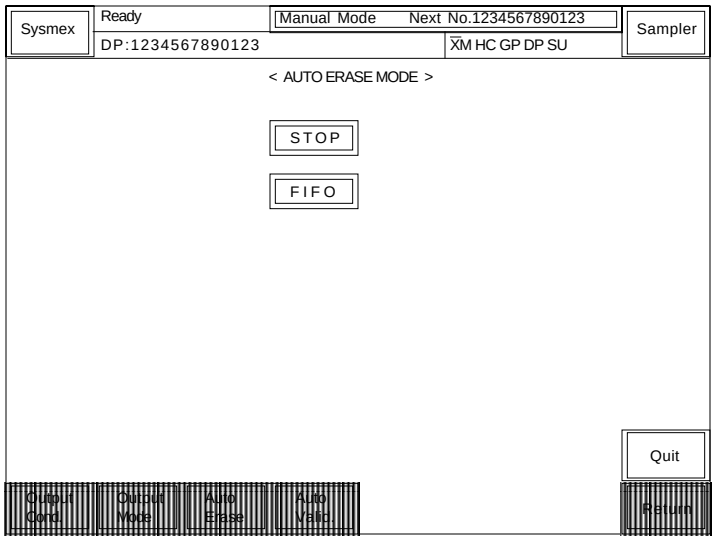


Figure 11-7: Auto Erase Setting Window

(3) Press the appropriate key to select the condition.

The auto erase conditions are as follows:

STOP : No data is automatically erased. Data will need to be erased manually when memory is full.

FIFO : Erase the oldest data automatically. This is the factory setting.

NOTE:	The factory setting is "FIFO".

(4) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Auto Erase setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Quit	:	To cancel the new settings. Program ends.

NOTE: When the remaining memory falls below for one sample capacity the "Data File Full" appears, stopping the analysis. Erase unneeded data using the Stored Data program and set Auto Erase to "FIFO" if needed.

2.4 Auto Validation

SF-3000 Auto Output function outputs only data that is validated for reporting. Use this program to accept previously specified sample data to output to the peripheral devices.

To set auto validation:

(1) Press [Auto Valid.] key in the Auto Management submenu.

(2) Enter the password and press [ENTER] key.
The Auto Validation setting screen containing current conditions will appear. The condition selected is marked by a "√".

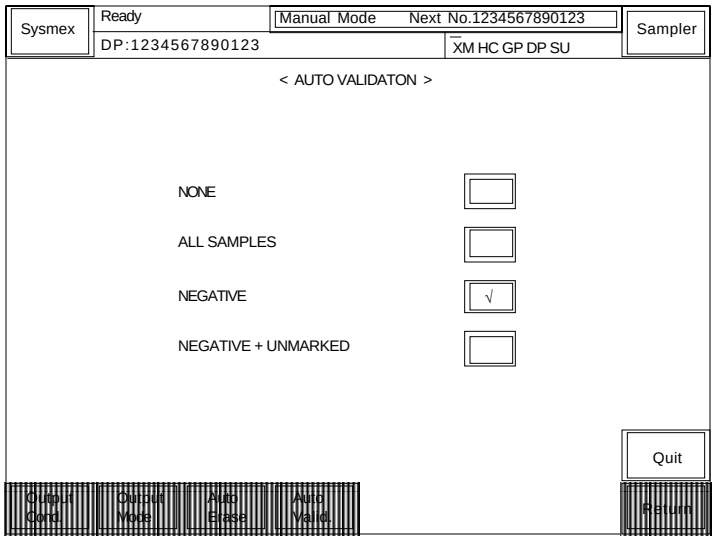


Figure 11-8: Auto Valid. Setting Window

(3) Press the appropriate key to select the condition.

The Auto Output program functions as follows when the auto validation condition is set to:

None	:	Auto output program outputs no samples.
All Samples	:	Auto output program outputs all samples.
Negative	:	Auto output program outputs all negative samples.
Negative+Unmarked	:	Auto output program outputs all negative samples not exceeding their mark limits set in the Mark Limits program.

NOTE: The factory setting is "None".

> **NOTE:** Refer to *Chapter 4, Section 13* for Auto Output program.

(4) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Auto Valid. setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Quit	:	To cancel the new settings. Program ends.

3. DATA CRITERIA

Use this program to set the following criteria.

- Mark Limits, which will monitor and add a flag when a parameter is outside the acceptable data range.
- Critical Limits, which will monitor and add an explanation mark when a parameter is life threatening value or unreliable.
- Stop Limits, which will monitor and stops auto mode analysis when a parameter is outside the acceptable data range.
- Stop Conditions, which will monitor and stops auto mode analysis when a specified error occurs.

To execute data criteria programs:

(1) Press the [Settings] key in the root menu. The Settings second menu will be displayed.

> **NOTE:** If the [Settings] keypad is not displayed on the LCD, press the [More] key to change the displayed root menu.

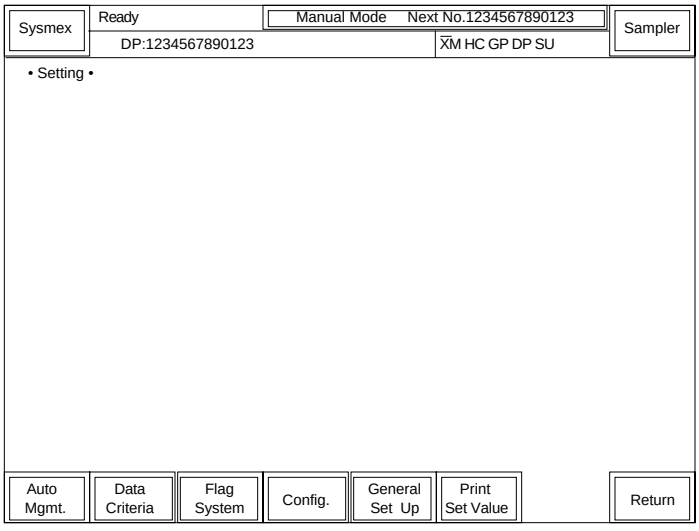


Figure 11-9: Settings Second Menu Screen

(2) Press [Data Criteria] key in the second menu. The Input Password window shown below will appear. Input the registered password and press the [ENTER] key.

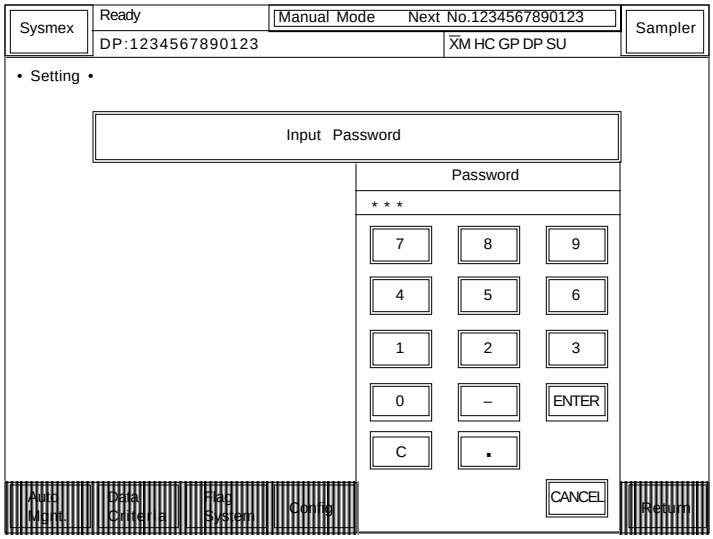


Figure 11-10: Password Input Window

(3) The Data Criteria submenu appears as shown in Figure 11-11.

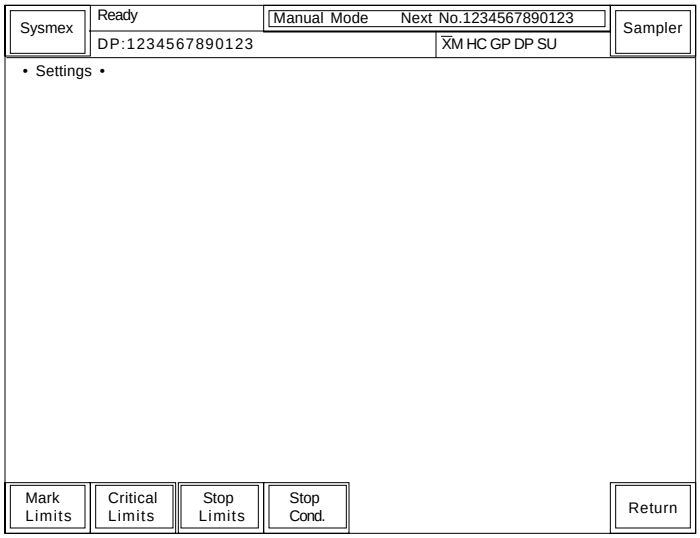


Figure 11-11: Data Criteria Submenu Screen

(4) Press the desired keypad to execute the program. Proceed each program by referring to the following sections.

(5) When [Quit] key is pressed to exit the setting program, the confirmation message window will appear. Press the appropriate key [Continue], [Set] or [Cancel].

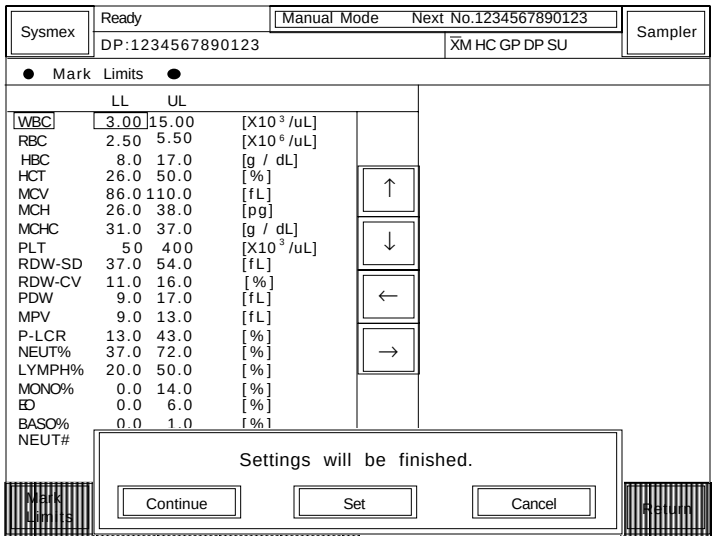


Figure 11-12: Example of End of Setting Window

Continue : To return to the previous screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

3.1 Mark Limits

Use this program to set the upper and lower mark limits.
If a parameter is outside of the upper or lower mark limit, a "+" or "-" will appear to the right of that parameter respectively. Mark limits of analysis data output by DP, GP or HC also use these upper and lower limits.

To set mark limit:

(1) Press [Mark Limits] key in the Data Criteria submenu. The Mark Limits setting screen containing the current setting values and numeric keys will appear.

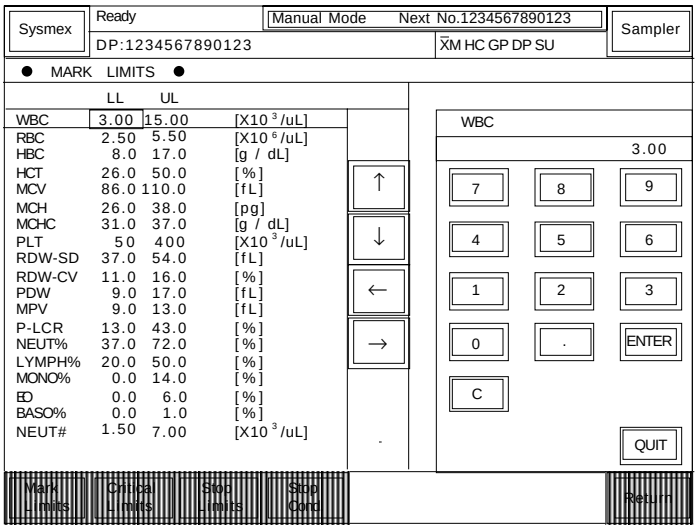


Figure 11-13: Mark Limits Setting Window

NOTE: The settings illustrated on the screen above are the factory settings.

(2) Use the [↑] and [↓] keys to select a parameter.

Use the [←] and [→] keys to select the upper or lower limit. The current value for the selected limit will be displayed above the numeric keys.

NOTE:
- All 23 parameters are present for setting, but all of them cannot fit into a single screen; use the [↑] and [↓] keys to scroll up and down.
- Pressing [ENTER] key after inputting the new value has the same effect as pressing the [→] key.

(3) Input the new limits using the numeric keys and press [ENTER].

> **NOTE:** If you do not want to use a particular parameter in the mark limits, set zero for the lower limit and set a very high value (e.g. 999.9) for the upper limit.

(4) Press [QUIT] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Mark Limits setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

3.2 Critical Limits

Use this program to set the upper and lower limits for critical judgment.
The critical limits are used to call attention to life threatening values or to judge data as unreliable. An exclamation mark (!) with a red back-light will appear to the right of analysis data that falls outside of the critical limits. However, this exclamation mark will not appear with data output via DP, GP or HC, only appears on the screen.

NOTE: "Data judged unreliable according to the Critical Limits" means data falls outside of the normal analysis range due to instrumental abnormality, patient abnormal values, cell morphology, etc.

To set critical limits:

(1) Press [Critical Limits] key in the Data Criteria submenu.
The Critical Limits setting screen containing the current setting values and numeric keys will appear.

(2) Use the [↑] and [↓] keys to select a parameter.

Use the [←] and [→] keys to select the upper or lower limit. The current value for the selected limit will be displayed above the numeric keys.

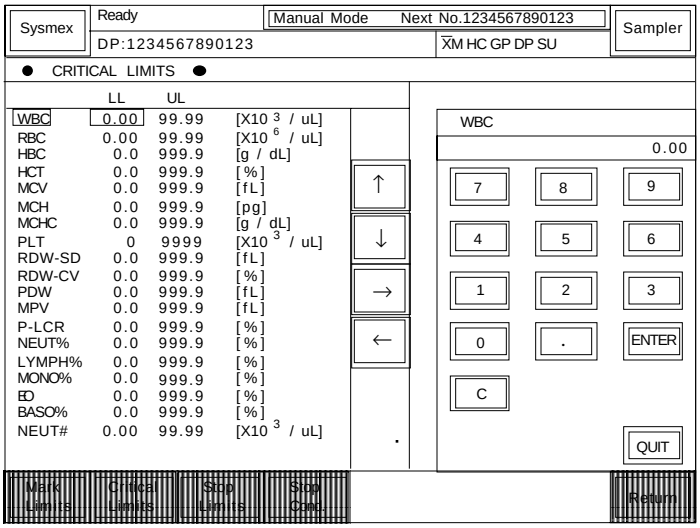


Figure 11-14: Critical Limits Setting Window

NOTE: The settings illustrated on the screen above are the factory settings.

NOTE:
- All 23 parameters are present for setting, but all of them cannot fit into a single screen; use the [↑] and [↓] keys to scroll up and down.
- Pressing [ENTER] key after inputting the new value has the same effect as pressing the [→] key.

(3) Input the new limits using the numeric keys and press [ENTER].

(4) Press [QUIT] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Critical Limits setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

3.3 Sampler Stop Limits

Use this program to set the upper and lower limits used for stopping auto mode analysis. A "+" or "-" with a red back-light will appear on the screen to the right of analysis data that falls outside of the sampler stop limits.

NOTE: "+" and "-" will not appear with data output via DP, GP or HC.

To set sampler stop limits:

(1) Press [Stop Limits] key in the Data Criteria submenu.
The Stop Limits setting screen containing the current setting values and numeric keys will appear.

(2) Use the [↑] and [↓] keys to select a parameter.

Use the [←] and [→] keys to select the upper or lower limit. The selected limit will be displayed above the numeric keypads.

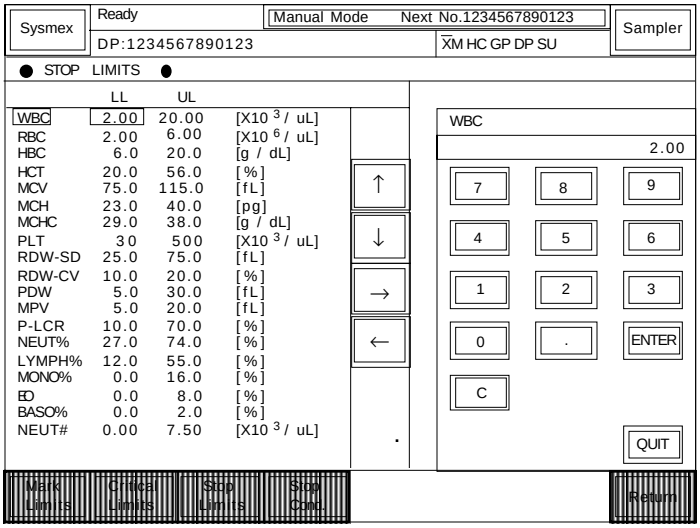


Figure 11-15: Stop Limits Setting Window

NOTE: The settings illustrated on the screen above are the factory settings.

NOTE:
- All 23 parameters are present for setting, but all of them cannot fit into a single screen; use the [↑] and [↓] keys to scroll up and down.
- Pressing [ENTER] key after inputting the new value has the same effect as pressing the [→] key.

(3) Input the new limits using the numeric keys and press [ENTER].

NOTE: If you do not want to use a particular parameter in the stop limits, set zero for the lower limit and set a very high value (e.g. 999.9) for the upper limit.

(4) Press [QUIT] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Stop Limits setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

3.4 Sampler Stop Condition

Use this program to set the sampler (auto mode) analysis stop conditions.
The SF-3000 will stop sampler analysis when an error occurs if the conditions for the error are enabled in the sampler stop conditions program.

To set sampler stop conditions:

(1) Press [Stop Cond.] key in the Data Criteria submenu.
The Stop Conditions setting screen containing the current setting conditions will appear.

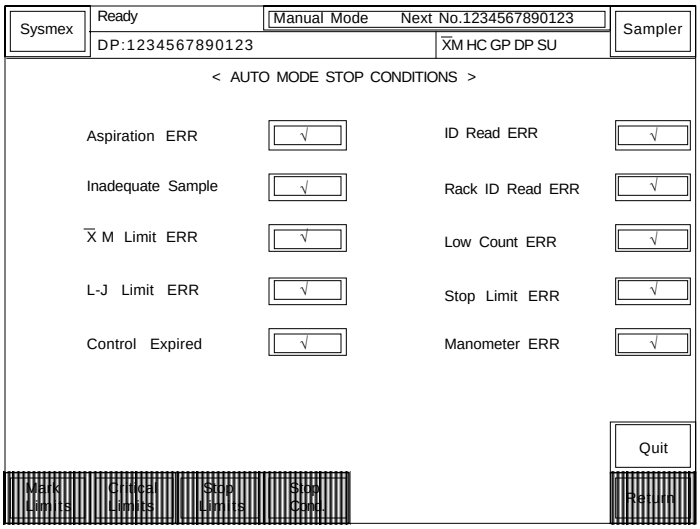


Figure 11-16: Sampler Stop Conditions Setting Window

NOTE:	The conditions illustrated on the screen above are the factory settings.

The following errors can be specified as conditions for stopping auto mode analysis:

Aspiration ERR	:	Analysis stops if "Blood Asp Sensor Error", "Sample Not Asp Error", or "Short Sample" occurs.
Inadequate Sample	:	Analysis stops if the Blood Volume Sensor detects a short sample.
$\overline{X}_M$ Limit ERR	:	Analysis stops if $\overline{X}_M$ limit error occurs.
L-J Limit ERR	:	Analysis stops if L-J limit error occurs.
ID Read ERR	:	Analysis stops if sample ID No. cannot be read.
Control Expired	:	Analysis stops if analyzed control lot of SF CHECK is expired.
Rack ID Read ERR	:	Analysis stops if rack ID No. cannot be read.
Low Count ERR	:	Analysis stops if sample with extremely low count value occurs.
Stop Limit ERR	:	Analysis stops if sampler stop limit error occurs.
Manometer ERR	:	Analysis stops if "RBC Slow To Start", "RBC Count Too Long", "RBC Fast To Start", or "RBC Count Too Short" occurs.

(2) Press the box key to the right of each item to select the condition. The selected conditions will be marked by a "√". To disable the setting for the condition, press the key pad marked "√".
(The factory setting is "√" for all conditions.)

(3) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Stop Conditions setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

4. FLAG SYSTEM

Use this program to set the Abnormal IP Message limits for WBC, RBC and PLT. When analysis data of a sample is outside of the limit, the data will be flagged with an IP message to indicate abnormal status of the data.

NOTE: The limits for the Suspect IP messages cannot be changed.

To set abnormal limits:

(1) Press [Settings] key in the root menu. The Settings second menu will be displayed.

NOTE: If the [Settings] keypad is not displayed on the LCD, press [More] key to change the displayed root menu.

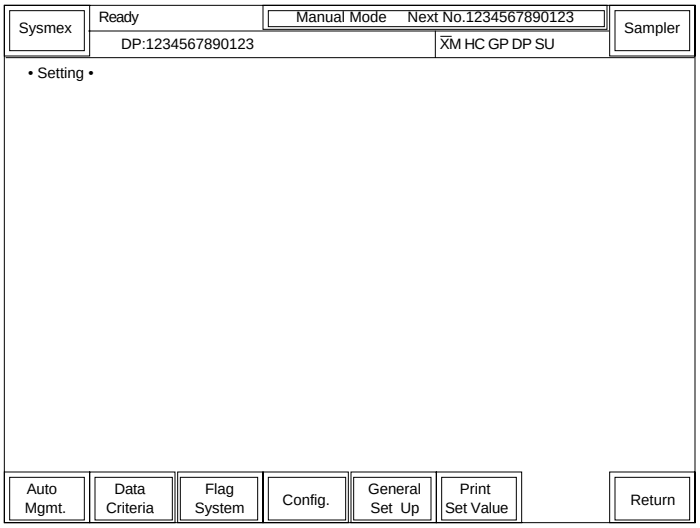


Figure 11-17: Settings Second Menu Screen

(2) Press [Flag System] key in the second menu. The password input screen shown below will appear. Input the registered password and press the [ENTER] key.

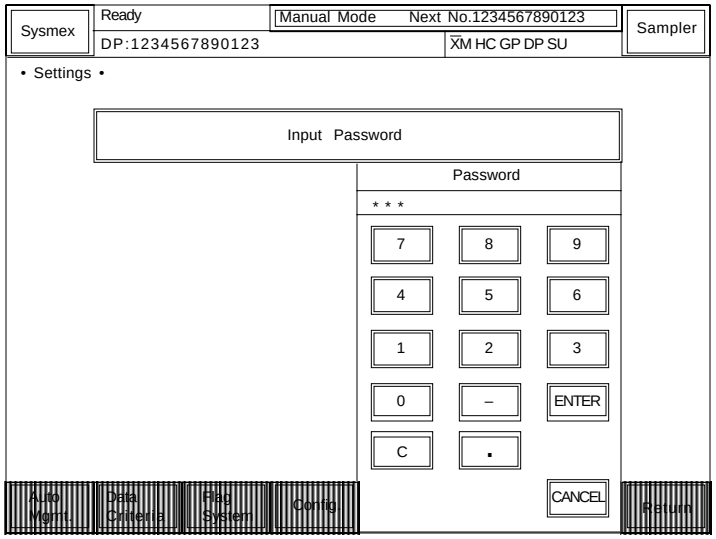


Figure 11-18 Password Input Window

(3) The Flag System submenu appears as shown in Figure 11-19.

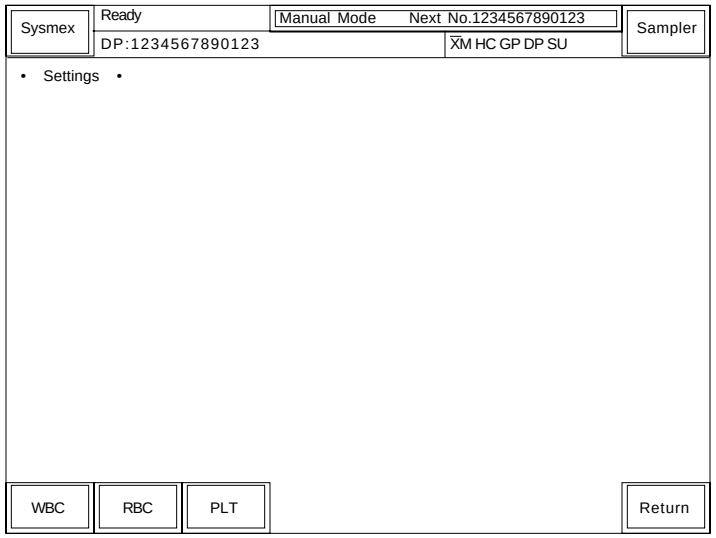


Figure 11-19: Flag System Submenu Screen

(4) Press the desired keypad to execute the program. Proceed each program by referring to the following sections.

(5) When [QUIT] key is pressed to exit the setting program, the confirmation message window will appear. Press the appropriate key [Continue], [Set] or [Cancel].

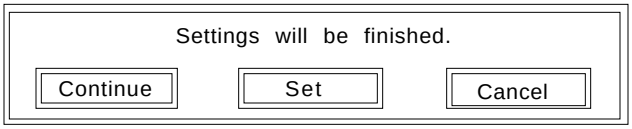


Figure 11-20: End of Setting Window

Continue : To return to the previous screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

4.1 WBC

Use this program to set IP message limits for WBC.

To set abnormal limits for WBC:

(1) Press [WBC] key in the Flag System submenu.
The WBC setting screen containing the current settings for the various IP messages and numeric keys will appear.

(2) Use the [↑] and [↓] keys to select the desired abnormal message and setting item.

(3) Use the numeric keys to input the new limit value. Press [ENTER] to input the values and move to the next item.

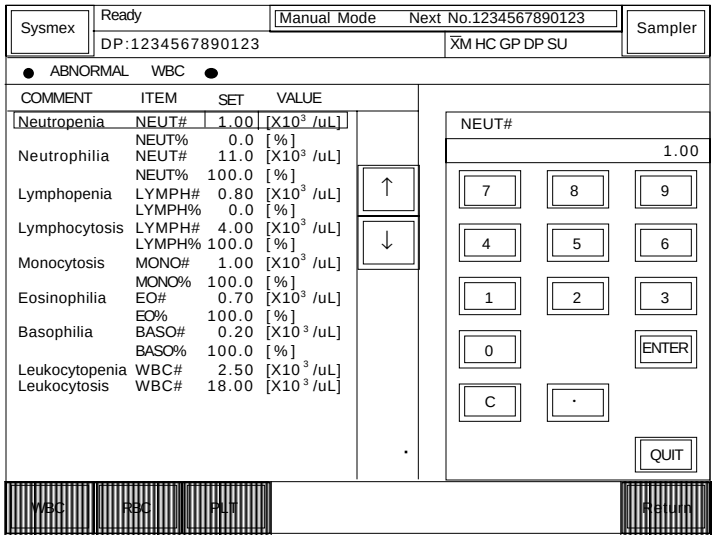


Figure 11-21: WBC Flag System Setting Window

NOTE: The factory settings are given in Table 11-2.

Table 11-2: WBC Abnormal IP Messages (The Factory Settings)

Item No.	Message	Message occurs when
2	Neutropenia (*)	NEUT#<1.00 [x 10^3/µL], or NEUT%<0.0[%]
3	Neutrophilia (*)	NEUT#>11.00 [x 10^3/µL], or NEUT%>100.0[%]
4	Lymphopenia (*)	LYMPH#<0.80 [x 10^3/µL], or LYMPH%<0.0[%]
5	Lymphocytosis (*)	LYMPH#>4.00 [x 10^3/µL], or LYMPH%>100.0[%]
6	Monocytosis (*)	MONO#>1.00 [x 10^3/µL], or MONO%>100.0[%]
7	Eosinophilia (*)	EO#>0.70 [x 10^3/µL], or EO%>100.0[%]
8	Basophilia (*)	BASO#>0.20 [x 10^3/µL], or BASO%>100.0[%]
9	Leukocytopenia	WBC#<2.50 [x 10^3/µL]
A	Leukocytosis	WBC#>18.00 [x 10^3/µL]

NOTE:

- WBC IP messages are displayed in the order of their Item Nos. Messages with smaller Item Nos. are displayed first followed by those with larger Item Nos.
- For the factory settings shown in Table 11-2 above, messages marked with an asterisk (*) are set to be judged using absolute # values not % values.
- If your laboratory is going to judge using % value, you have to adjust the values as below so one or the other is utilized for judgment.

Example)

2. Neutropenia	NEUT#	<	0.00 [x 10^3/µL]
	NEUT%	<	20.0 [%]
3. Neutrophilia	NEUT#	>	99.99 [x 10^3/µL]
	NEUT%	>	85.0 [%]

(4) Press [QUIT] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue : To return to WBC setting screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

4.2 RBC

Use this program to set IP message limits for RBC.

To set abnormal limits for RBC:

(1) Press [RBC] key in the Flag System submenu.
The RBC setting screen containing the current settings for the various IP messages and numeric keys will appear.

(2) Use the [↑] and [↓] keys to select the desired abnormal message and setting item.

(3) Use the numeric keys to input the new limit value. Press [ENTER] to input the values and move down to the next item.

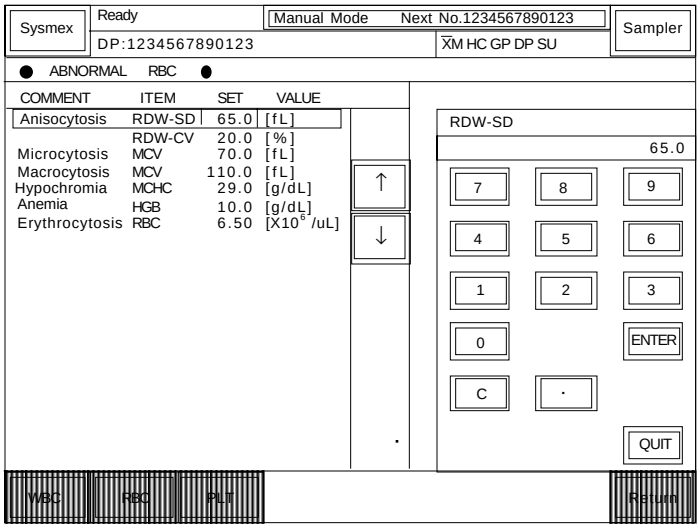


Figure 11-22: RBC Flag System Setting Window

NOTE:	The factory settings are given in Table 11-3.

Table 11-3 : RBC Abnormal IP Messages (The Factory Settings)

Item No.	Message	Message occurs when
3	Anisocytosis	RDW-SD > 65.0 [fL], or RDW-CV > 20.0 [%]
4	Microcytosis	MCV < 70.0 [fL]
5	Macrocytosis	MCV > 110.0 [fL]
6	Hypochromia	MCHC < 29.0 [g/dL]
7	Anemia	HGB < 10.0 [g/dL]
8	Erythrocytosis	RBC > 6.50 [x 10^6/μL]

NOTE: RBC IP messages are displayed in the order of their Item Nos. Messages with smaller Item Nos. are displayed first, followed by those with larger Item Nos.

(4) Press [QUIT] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue : To return to RBC setting screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

4.3 PLT

Use this program to set IP message limits for PLT.

To set abnormal limits for PLT:

(1) Press [PLT] key in the Flag System submenu.
The PLT setting screen containing the current settings for the various IP messages and numeric keys will appear.

(2) Use the [↑] and [↓] keys to select the desired abnormal message and setting item.

(3) Use the numeric keys to input the new limit value. Press [ENTER] to input the values and move down to the next item.

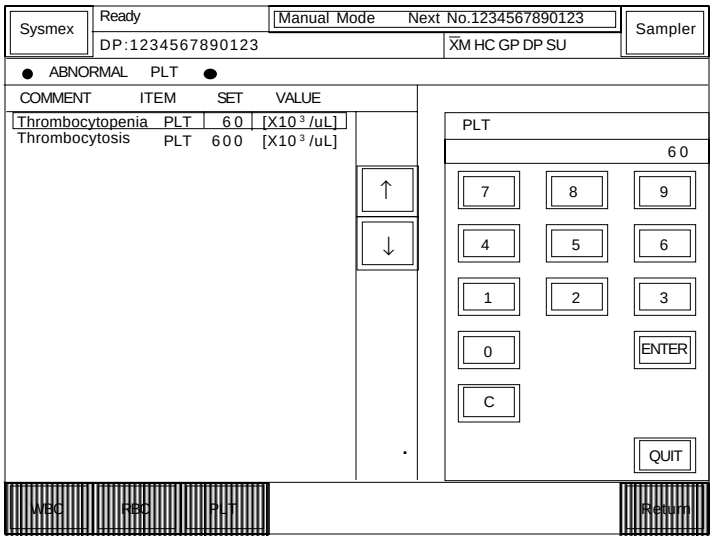


Figure 11-23: PLT Flag System Setting Window

Table 11-4 : PLT Abnormal IP Messages (The Factory Settings)

Item No.	Message	Message occurs when
2	Thrombocytopenia	PLT < 60 [x $10^3/\mu L$]
3	Thrombocytosis	PLT > 600 [x $10^3/\mu L$]

NOTE: The factory settings are given in Table 11-4.

NOTE: PLT IP messages are displayed in the order of their Item Nos. Messages with smaller Item Nos. are displayed first, followed by those with larger Item Nos.

(4) Press [QUIT] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue : To return to PLT setting screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

5. PERIPHERAL CONFIGURATION

Use this program to set printer output conditions, print formats and the Host Computer interface parameters.

To set configuration of peripheral devices:

(1) Press [Settings] key in the root menu. The Settings second menu will be displayed.

NOTE: If the [Settings] keypad is not displayed on the LCD, press [More] key to change the displayed root menu.

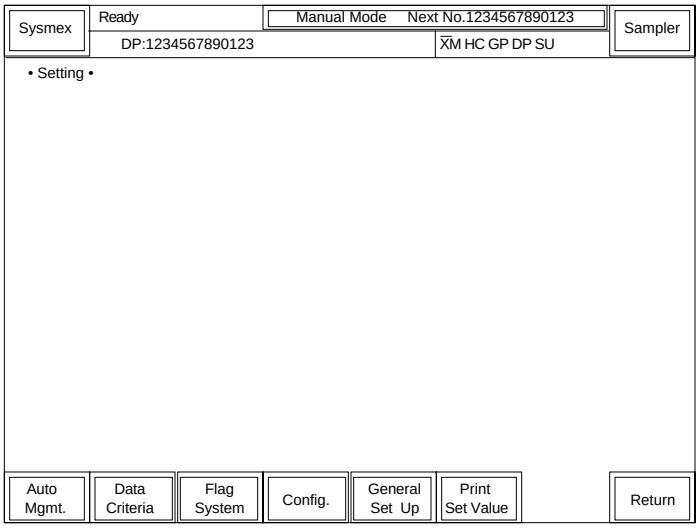


Figure 11-24: Settings Second Menu Screen

(2) Press [Config.] key in the second menu.

(3) The password input screen shown below will appear. Input the registered password and press the [ENTER] key.

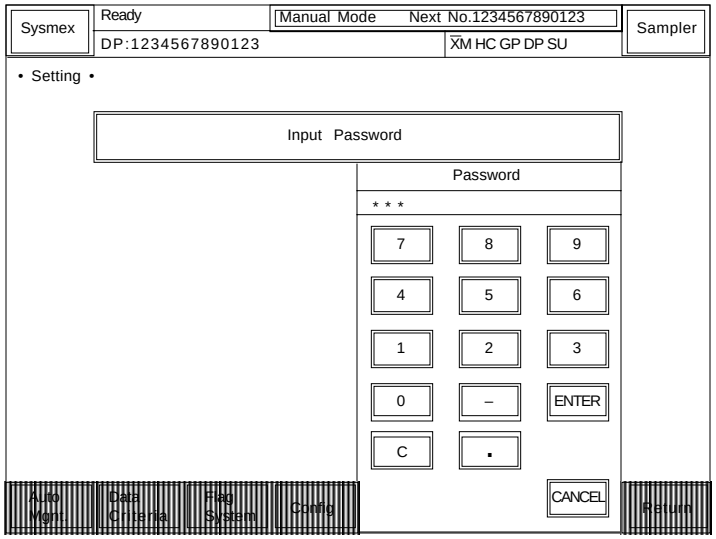


Figure 11-25: Password Input Window

(4) The Configuration submenu appears as shown in Figure 11-26.

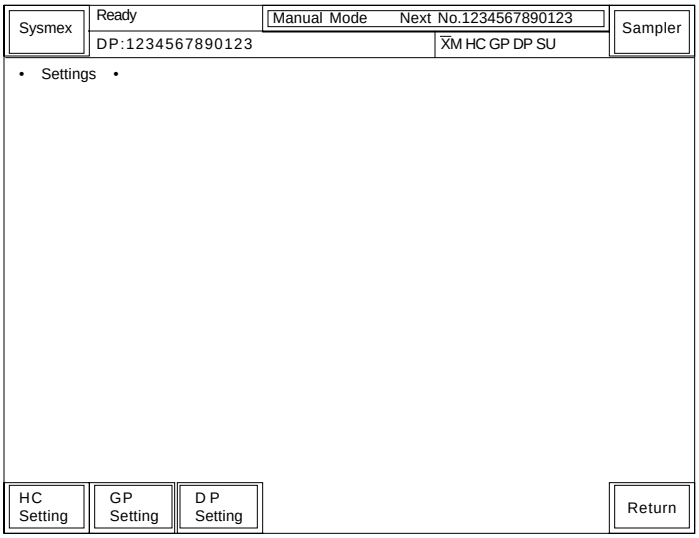


Figure 11-26: Configuration Submenu Screen

(5) Press the desired keypad to execute the program. Proceed each program by referring to the following sections.

(6) When [Quit] key is pressed to exit the setting program, the confirmation message window will appear. Press the appropriate key [Continue], [Set] or [Cancel].

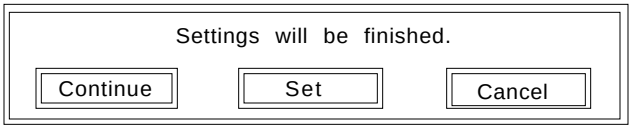


Figure 11-27: End of Setting Window

Continue : To return to the previous screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

5.1 HC Setting (Host Computer)

Use this program to set interface conditions for the Host Computer.

To set interface conditions for HC output:

(1) Press [HC Setting] key in the Configuration submenu.
The HC setting screen will appear, containing the current interface conditions. The selected parameter is backlit in light-blue or a check mark (√) is placed in the box to the right of selected item.

(2) Press the appropriate keys to select the condition.

(3) There are two screens for HC settings. Press [More] key to alter the screen.

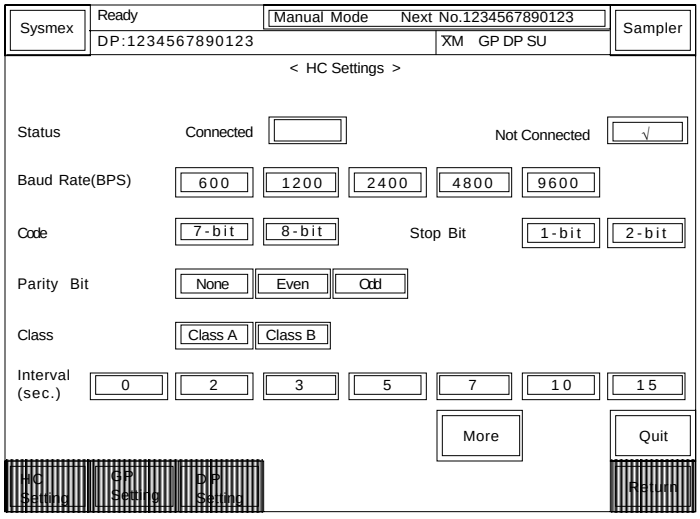


Figure 11-28: HC Setting Screen - 1

Status : When the Host Computer is connected, select "Connected". If "Not Connected" is selected, "HC" will not appear in the LCD system status display area. (The factory setting is "Not Connected".)

Baud Rate : The baud rate can be selected. (The factory setting is "2400" bps.)

Code : The data bit length can be selected. (The factory setting is "7-Bit".)

Stop Bit : The stop bit length can be selected. (The factory setting is "2-Bit".)

Parity Bit : The parity bit can be selected. (The factory setting is "Even".)

Class : The transmission procedure protocol can be selected. (The factory setting is "Class A".)

Interval : Time interval between data transmitted to the Host Computer can be selected. (The factory setting is "2" seconds.)

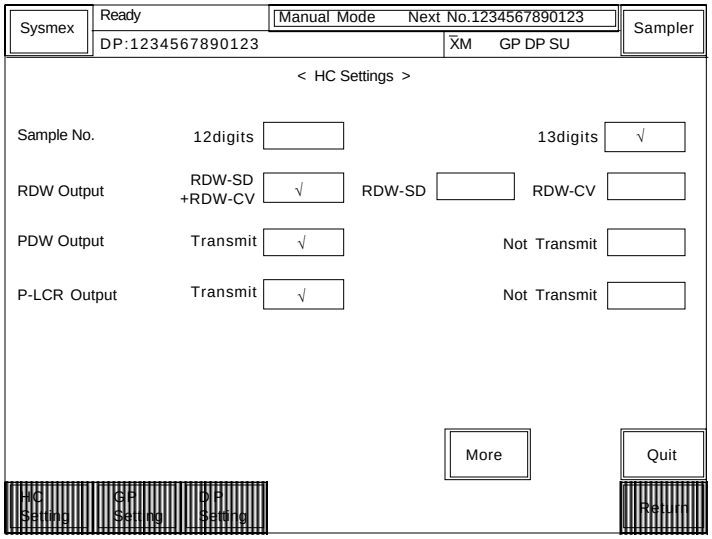


Figure 11-29: HC Setting Screen - 2

Sample No. : Either "12 digits" or "13 digits" can be selected. (The factory setting is "13 digits".)

RDW Output : RDW output can be selected.
(The factory setting is "RDW-SD + RDW-CV".)

PDW Output : Either "Transmit" or "Not Transmit" can be selected.
(The factory setting is "Transmit".)

P-LCR Output : Either "Transmit" or "Not Transmit" can be selected.
(The factory setting is "Transmit".)

(4) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue : To return to HC setting screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

5.2 GP Setting (Graphic Printer)

Use this program to set interface conditions for the Graphic Printer.

To set GP interface conditions:

(1) Press [GP Setting] key in the Configuration submenu.
The GP setting screen will appear, containing the current interface conditions. The selected parameter is backlit in light-blue or a check mark (√) is placed in the box to the right of selected item.

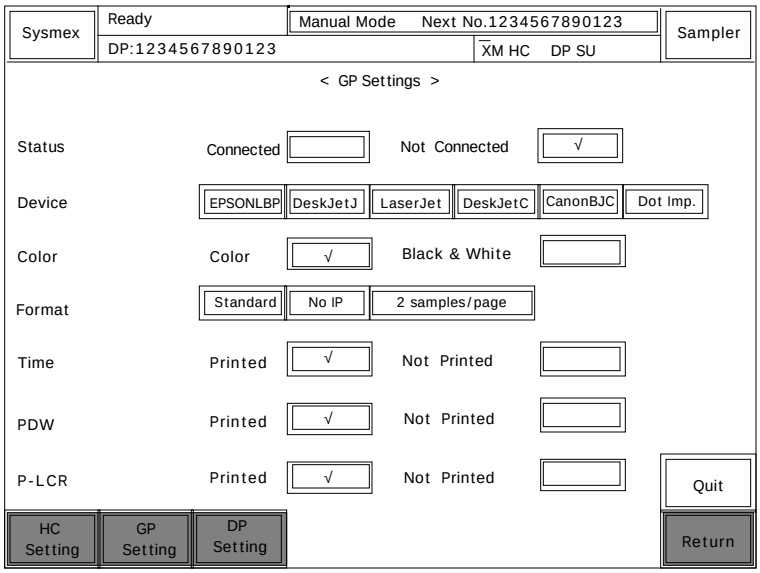


Figure 11-30: GP Setting Window

(2) Press the appropriate key to select the condition.
The conditions available for selection are as follows:

Status : When the Graphic Printer is connected, select "Connected". If "Not Connected" is selected, "GP" will not appear in the LCD system status display area. (The factory setting is "Not Connected".)

Device : Select the printer model. (The factory setting is "DeskJetC".)

- EPSONLBP : Select this for the Line Printer model LP-1500 or LP-1600.
- DeskJet J : Select this for the Graphic Printer model DeskJet 560J (for Japanese domestic market).
- LaserJet : Select this for the Graphic Printer model LaserJet.
- DeskJet C : Select this for the Graphic Printer model DeskJet 560C.
- Canon BJC : Select this for the Graphic Printer model Canon BJC 400J (for Japanese domesticmarket).
- Dot Imp. : Select this for the dot impact printer model OKI MICROLINE 320.

Color : Either "Color" or "Black&White" display can be selected.
When the printer model "EPSONLBP" or "LaserJet" is selected, set to "Black&White". Color printing is not available using these printer models.
When the "DeskJetC" is selected, either setting is available according to its ink cassette.
(The factory setting is "Color".)

> **NOTE:** Printing time is shorter with "Black&White" setting than with "Color".

Format : When the "Standard" is selected, IP Massages can be printed following the scattergram.
When the "No IP" is selected, no IP Message will be printed and free space can be used on the lower half of the page.
When the "2 samples/page" is selected, two sample data without IP Messages can be printed on one page, when Mark Data output and Auto Output is performed.

Time : Either "Printed" or "Not Printed" can be selected for the time when sample was analyzed. (The factory setting is "Printed".)

PDW : Either "Printed" or "Not Printed" can be selected for PDW data. (The factory setting is "Printed".)

P-LCR : Either "Printed" or "Not Printed" can be selected for P-LCR data. (The factory setting is "Printed".)

(3) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue : To return to GP setting screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

5.3 DP Setting (Data Printer)

Use this program to set the print parameters for the data printer (card printer).

To set DP print parameters:

(1) Press [DP Setting] key in the Configuration submenu.
The DP setting screen will appear, containing the current print parameters. The selected parameter is backlit in light-blue or a check mark (√) is placed in the box to the right of selected item.

(2) Press the appropriate keypads to select the condition.

(3) There are two screens for DP settings. Press [More] key to alter the screens.

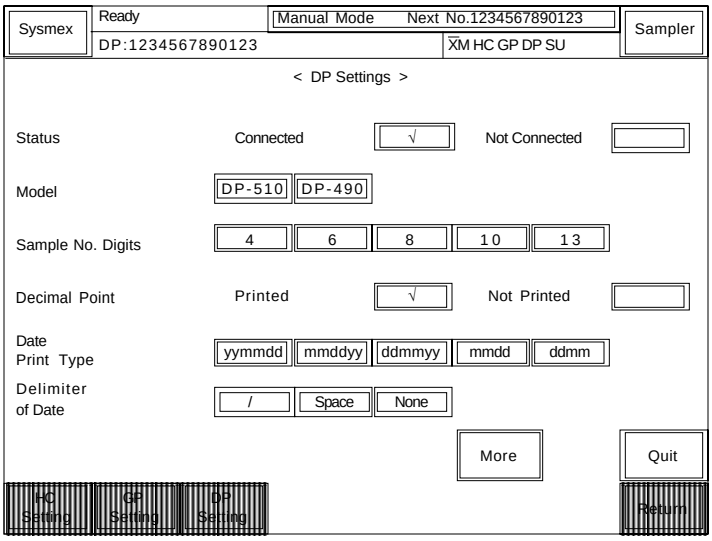


Figure 11-31: DP Setting Screen - 1

Status : When the Data Printer is connected, select "Connected". If "Not Connected" is selected, "DP" will not appear in the LCD system status display area. (The factory setting is "Connected".)

Model : Select the model "DP-510" or "DP-490". (The factory setting is "DP-510".)

Sample No. Digits : Set the maximum number of digits for sample ID Nos. ID Nos. can be set 4, 6, 8, 10 or 13 digits. ID Nos. will be printed in order of the lowest number of digits to the highest number of digits with the maximum number of digits being the value set here. (The factory setting is "13 digits".)

Decimal Point : Specify whether the decimal point is to be printed in the data or not. Select "Printed" or "Not Printed". (The factory setting is "Printed".)

Date Print Type : Select one of the date print formats. (The factory setting is "mmddyy".)

Delimiter of Date : Three different delimiters can be used between the figures for day, month and year. (The factory setting is "/".)

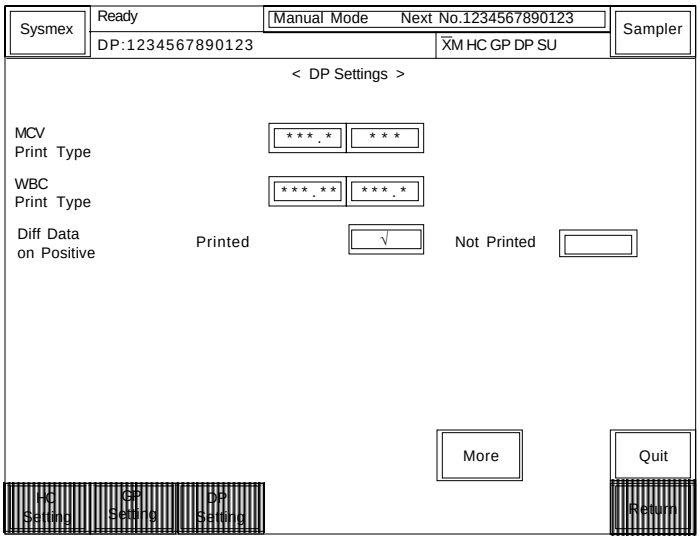


Figure 11-32: DP Setting Screen - 2

MCV Print Type : Specify whether numerals after the decimal point are to be printed for MCV data.
(The factory setting is "***.*".)

> **NOTE:** If numerals after the decimal place are not printed for MCV, the number before the decimal place is rounded up or down to the nearest unit.

WBC Print Type : Select the WBC print format. The options are "***.**" (5 digits) and "***.*" (4 digits).
(The factory setting is "***.**".)

DIFF Data on Positive : Use this program to specify whether the WBC 5 part differential results for a Positive Sample are to be printed or not. (The factory setting is "Printed".)

(4) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue : To return to DP setting screen so that setting can be continued.
Set : To save the new settings. Program ends.
Quit : To cancel the new settings. Program ends.

6. GENERAL SET UP

Use this program to set SF-3000 system status.

To execute General Set Up programs:

(1) Press [Settings] key in the root menu. The Settings second menu will be displayed.

> **NOTE:** If the [Settings] keypad is not displayed on the LCD, press [More] key to change the displayed root menu.

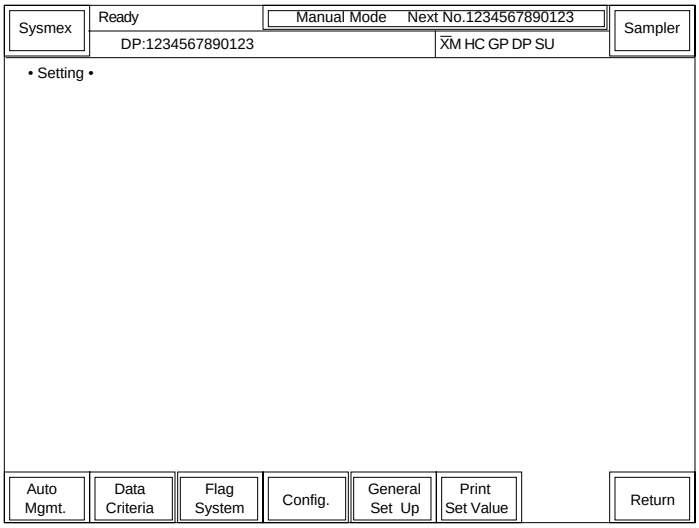


Figure 11-33: Settings Second Menu Screen

(2) Press [General Set Up] key in the second menu. The password input screen will appear.

> **NOTE:** When the [Date/Time] or [Date Format] key is pressed, the password entry is not required.

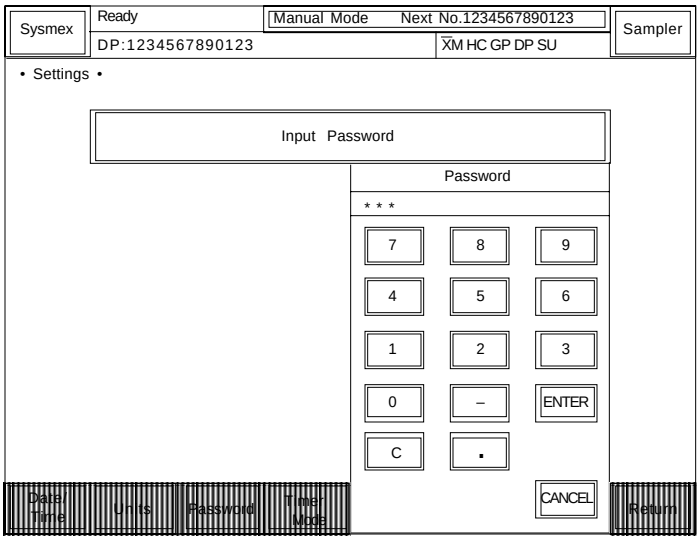


Figure 11-34: Password Input Window

(3) Input the registered password and press the [ENTER] key.

(4) The General Set Up submenu appears as shown in Figure 11-35.

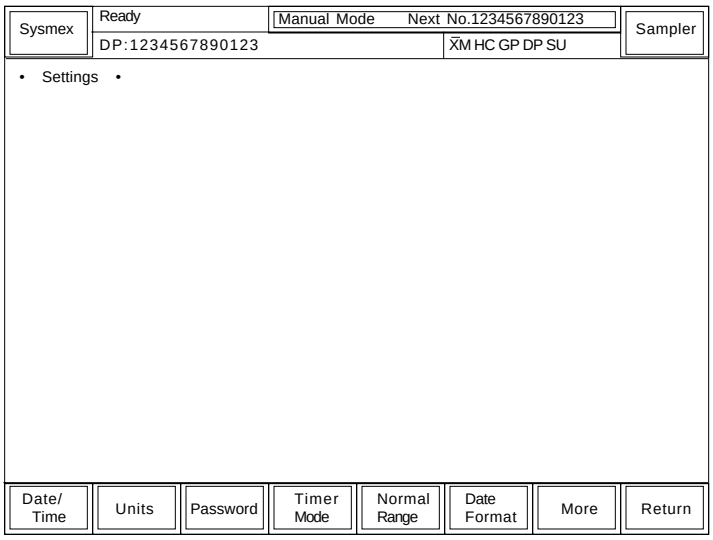


Figure 11-35: General Set Up Submenu Screen

(5) Press a desired keypad to execute a program. Proceed each program by referring to the following sections.

(6) When [Quit] key is pressed to exit the setting program, the confirmation message window will appear. Press the appropriate key [Continue], [Set] or [Cancel].

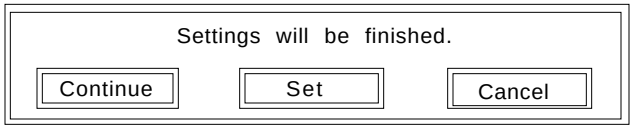


Figure 11-36: End of Setting Window

Continue : To return to the previous screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

6.1 Date/Time

The SF-3000 has a built-in clock that is powered by an internal battery whenever the power is turned off or interrupted, so that the date and time need only be reset occasionally.

To set date and time:

(1) Press [Date/Time] key in the General Set Up submenu.
The Date/Time setting screen containing the current date and time and numeric keys will appear.

(2) Move the green cursor with the [↑] and [↓] keys to select an item.

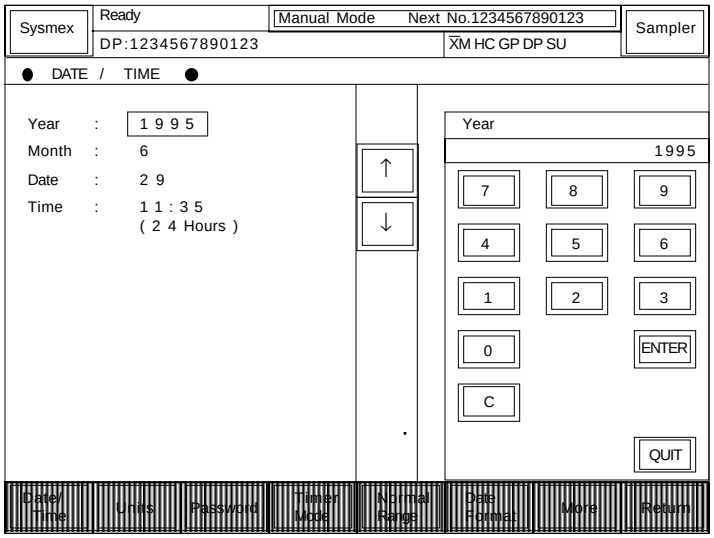


Figure 11-37: Date/Time Setting Screen

(3) Input date and time using the numeric keys and press [ENTER].
The current date or time is displayed above the numeric keys. The time appears in "hour : minute : second" format. To set time, input "hours" using numeric key, press [:] key, then input "minutes".

NOTE:
- When the time is selected for setting, [:] key will be added in the numeric keypads window.
- Time must be entered as a 24-hour system.
- "Seconds" can be entered and set but is not displayed or printed.

(4) Press [QUIT] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Date/Time setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

6.2 Units

Use this program to set the units used on the display and print outs.

To set units:

(1) Press [Units] key in the General Set Up submenu. The password input window will appear.

(2) Enter the password and press [ENTER] key.
The Units setting screen containing the current settings and numeric keys will appear.

(3) Use the [↑] and [↓] keys to select a parameter.

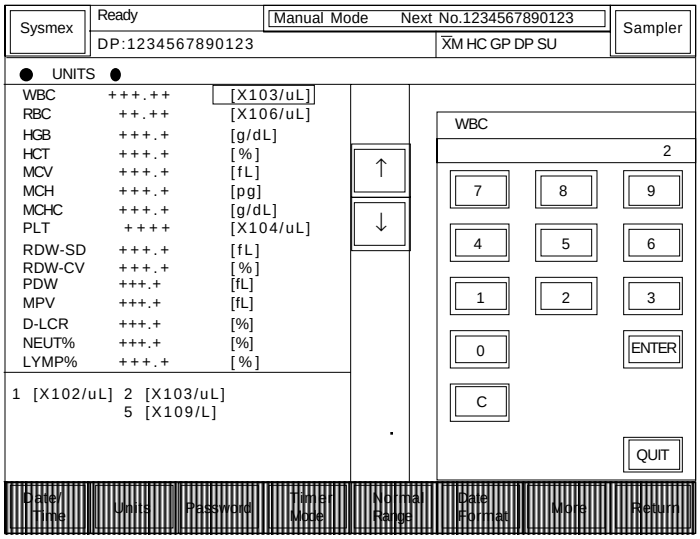


Figure 11-38: Units Setting Screen

(4) Press the appropriate unit number to input the unit number into the unit space. The numbers corresponding to a specific unit are displayed in the lower part of the screen.
Units available for the different parameters are as given below.

Table 11-5: Available Reporting Units

Parameter	Units Available	Unit No.
WBC	$x10^2$/µL, $x10^3$/µL, $x10^9$/L	1, 2, 5
RBC	$x10^4$/µL, $x10^6$/µL, $x10^{12}$/L	3, 4, 6
HGB	g/dL, g/L, mmol/L*	7, 8, 13
HCT	L/L, %, R, (None)	9, 10, 15, 17
MCV	fL	11
MCH	pg, fmol*, amol*	12, 14, 16
MCHC	g/dL, g/L, %, mmol/L*	7, 8, 10, 13
PLT	$x10^3$/µL, $x10^4$/µL, $x10^9$/L	2, 3, 5
RDW-SD	fL	11
RDW-CV	%, R, (None)	10, 15, 17
PDW	fL	11
MPV	fL	11
P-LCR	%, R, (None)	10, 15, 17
DIFF%	%, R, (None)	10, 15, 17
DIFF#	$x10^2$/µL, $x10^3$/µL, $x10^9$/L	1, 2, 5

CAUTION: When the Dutch SI units (mmol/L for HGB, fmol/amol for MCH, and mmol/L for MCHC) are selected, the Main Unit power has to be OFF, then ON to change the system units.
The units displayed on the screen will be changed without power OFF and ON but those on the analysis results display and output will not change.

(5) Press [QUIT] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue : To return to Units setting screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

6.3 Password

Use this program to change the password to be entered for log in.

To set the password:

(1) Press [Password] key in the General Set Up submenu. The Input Password window will appear.

(2) Enter the current password and press [ENTER] key.
The Password setting screen and numeric keys will appear.

(3) Input the new password and press [ENTER].
The password can consist of up to 12 digits. A beep will alert the operator if an incorrect value is entered.

> **CAUTION:** When the password is set to zero (0), the Input Password window will not appear. This will allow the operator to access any program without entering the password.

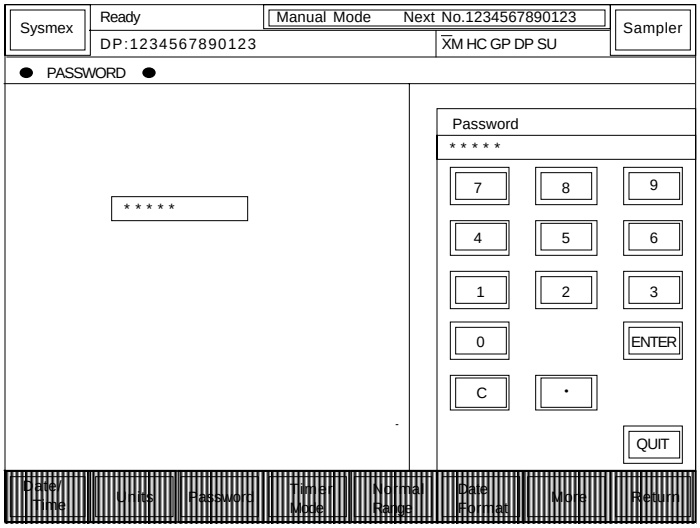


Figure 11-39: Password Setting Window

(4) Press [QUIT] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Password setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

6.4 Timer Mode

After sample analysis is complete and no key operation is performed within the set period of time, the timer can automatically switch off the power to the Pneumatic Unit. Use this program to set the time.

To set timer mode:

(1) Press [Timer Mode] key in the General Set Up submenu. The Input Password window will appear.

(2) Enter the password and press [ENTER] key.
The Timer Mode setting screen containing the current setting and numeric keys will appear.

(3) Input the period of time before the pneumatic unit is turned off. The available setting time is "in minutes" ranged from 1 to 15.
(The factory setting is "10" minutes.)

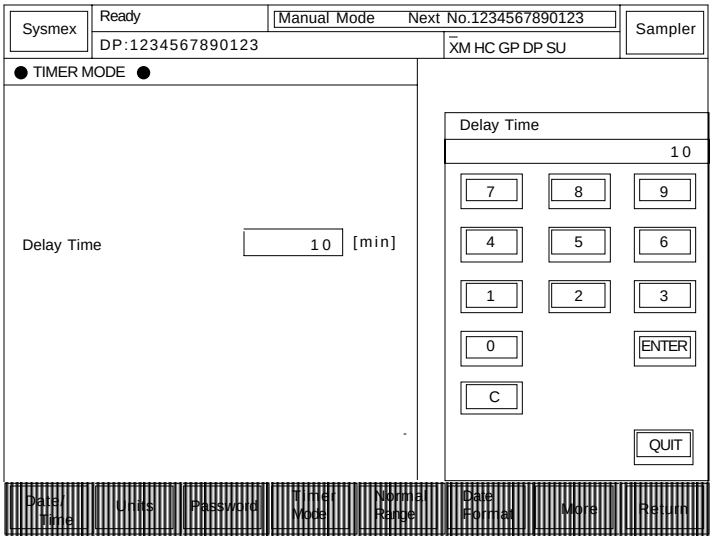


Figure 11-40: Timer Mode Setting Window

(4) Press [QUIT] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Timer Mode setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

6.5 Normal Range Display

Use this program to set whether or not normal range displays (Normograms) will appear on the graphic display screens, graphic printouts and hard-copy printouts.

To set normal range display:

(1) Press [Normal Range] key in the General Set Up submenu. The Input Password window will appear.

(2) Enter the password and press [ENTER] key.
The normal range display setting screen containing the current setting will appear.

(3) If "With Normal Range" is selected, a "√" mark is displayed on the screen. To disable the setting (to select "Without Normal Range"), press the key marked "√" again.

> **NOTE:** The factory setting is "With Normal Range" (marked with "√").

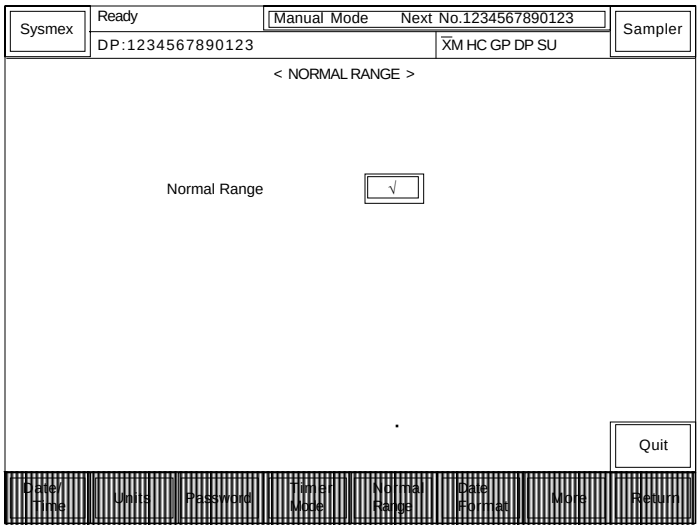


Figure 11-41: Normal Range Setting Window

(4) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Normal Range setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

(5) If "With Normal Range" is selected, normal ranges (normograms) will be displayed on the graphic display screens from the next analysis results display or a stored data display.

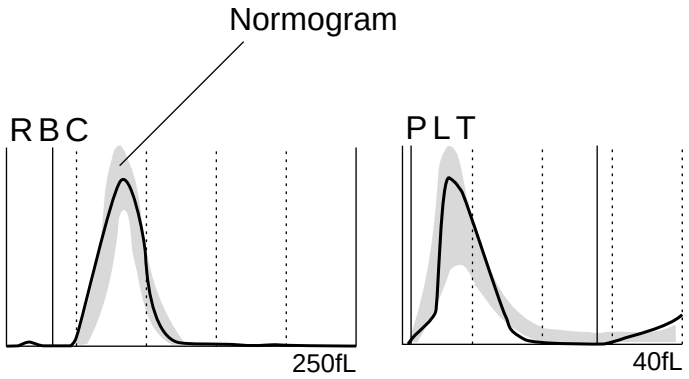


Figure 11-42: Normal Range Display

6.6 Date Format

Use this program to set the date format for the display and output of date.
There are 3 formats: "yymmdd", "mmddyy" or "ddmmyy".

> **NOTE:** The date format for the DP printout is set in the DP Setting program. Refer to *Section 5.3 DP Setting* in this chapter.

To set date format:

(1) Press [Date Format] key in the General Set Up submenu.
The Date Format setting screen will appear, containing the current date format setting.

(2) Press the appropriate key [yymmdd], [mmddyy] or [ddmmyy]. The selected format will be backlit in light-blue.
(The factory setting is "mmddyy".)

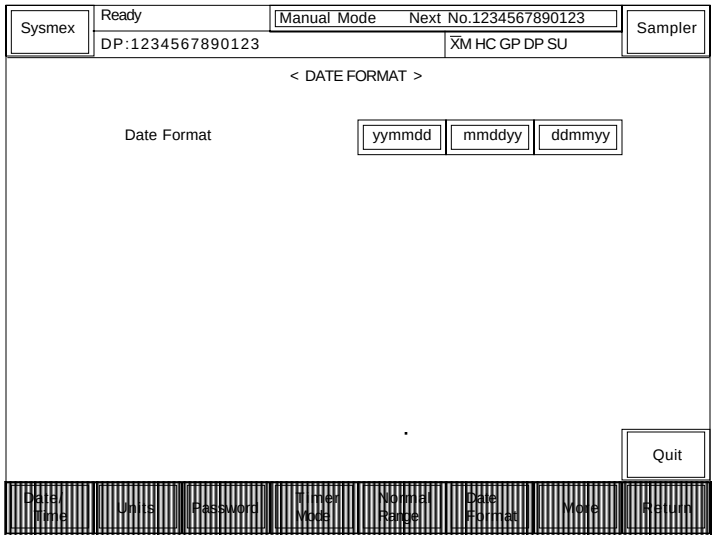


Figure 11-43: Date Format Setting Screen

(3) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to Date Format setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

6.7 ID Reader

Use this program to set the ID bar-code reader availability, type of bar code labels and check-digits required.

To set ID bar-code reader:

(1) Press [ID Reader] key in the General Set Up submenu. The Input Password window will appear.

NOTE :	If the [ID Reader] key is not displayed on the LCD, press [More] to change the displayed menus.

(2) Enter the password and press [ENTER] key.
The ID Reader setting screen will appear, containing the current reader availability, bar code labels and check-digits. The selected item will be backlit in light-blue or a mark "√" will be placed in the box on the right of selected item.

(3) Press the appropriate keys to select the condition.

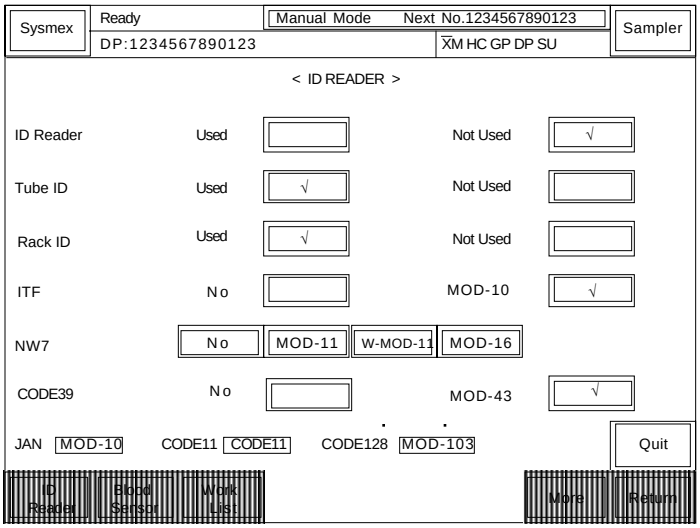


Figure 11-44: ID Reader Setting Window

The method and check-digit conditions available are as follows:

ID Reader : Select "Used" or "Not Used".
(The factory setting is "Not Used".)

Tube ID : Select "Used" or "Not Used" for test tube ID.
(The factory setting is "Used".)

Rack ID : Select "Used" or "Not Used" for rack ID.
(The factory setting is "Used".)

ITF (Interleaved 2 of 5)	:	Select either "No" or "MOD-10" for ITF bar-code check-digit. (The factory setting is "MOD-10".)
NW7	:	Select NW7 bar-code check digit. Options are "No", "MOD-11", "W-MOD-11", "MOD-16". (The factory setting is "MOD-11".)
CODE 39	:	Select "No" or "MOD-43" for the Code 39 bar-code check-digit. (The factory setting is "MOD-43".)
JAN	:	For JAN bar-code check-digit: "MOD-10". (The factory setting is "MOD-10".)
CODE 11	:	For CODE 11 bar-code check-digit: "CODE11". (The factory setting is "CODE11".)
CODE 128	:	For CODE 128 bar-code check-digits: "MOD-103". (The factory setting is "MOD-103".)

NOTE: For details of bar-code types and check-digits, see A*ppendix C: Technical Information*.

(4) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue	:	To return to ID Reader setting screen so that setting can be continued.
Set	:	To save the new settings. Program ends.
Cancel	:	To cancel the new settings. Program ends.

6.8 Blood Sensor

Use this program to set the use of the blood aspiration sensor.

To set blood sensor "Used" or "Not Used":

(1) Press [Blood Sensor] key in the General Set Up submenu. The Input Password window will appear.

(2) Enter the password and press [ENTER] key.
The Blood Sensor setting screen will appear, containing the current setting.

(3) When the sensor is set to "Used", a "√" mark is displayed on the screen. To disable the setting (not to use the sensor), press the key pad marked "√" again.

NOTE: The factory setting is "Used" (marked with "√").

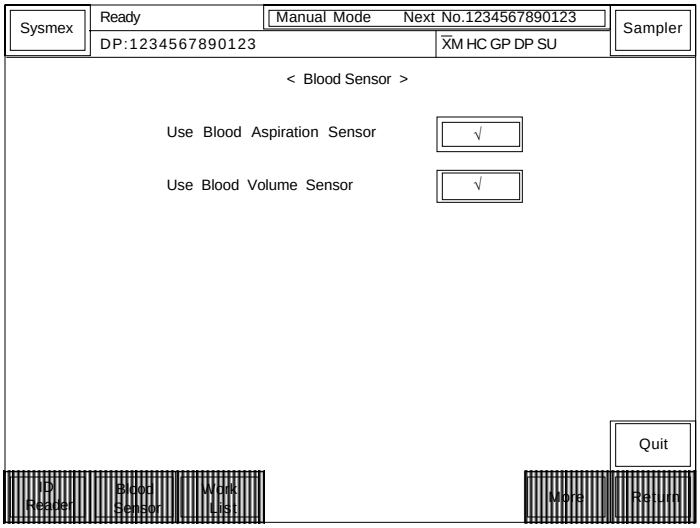


Figure 11-45: Blood Sensor Setting Window

Blood Aspiration Sensor : This sensor monitors the sample aspiration from the piercer in the Sampler Unit (closed line).
(The factory setting is "Used".)

NOTE: If it is known beforehand that samples of low volume or weak blood (like dialyzed patient's blood) are to be analyzed, set this option to "Not Used" condition by deselecting it (deleting the "√" mark).

Blood Volume Sensor : This sensor monitors if there is sample blood in a collection tube set in the sample rack.
(The factory setting is "Used".)

> **CAUTION:** If collection tubes with diameters of less than 12 mm are used, there is a possibility that the blood volume sensor detects no blood in the collection tube due to unstable tube position in the rack, and the system will skip the analysis of the sample. In this case, set this option to "Not Used" condition by deselecting it (deleting the "√" mark).
> However, please be advised that when the blood volume sensor is disabled, a sample of small amount is to be analyzed and this may cause "Short Sample" error. Make sure to verify prior to analysis that the sample volume is sufficient for analysis.

(4) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue : To return to Blood Sensor setting screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

6.9 Work List

Use this program to set the use of the Work List, and to set the key word for order inquiry.

To execute work list settings:

(1) Press [Work List] key in the General Set Up submenu. The Input Password window will appear.

(2) Enter the password and press [ENTER] key.
The Work List setting screen will appear, containing the current settings. A "√" mark is displayed for the selected item.

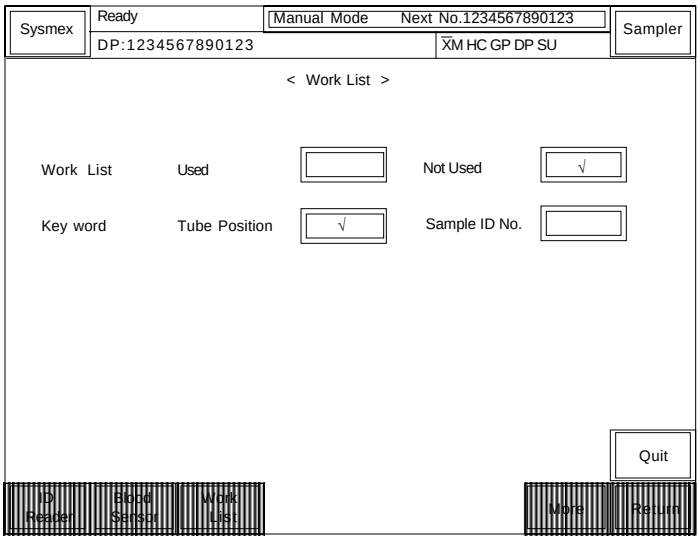


Figure 11-46: Work List Setting Window

Work List : Select "Used" or "Not Used".
(The factory setting is "Not Used".)

Keyword : Select "Tube Position" or "Sample ID No." for the key word for order inquiry (The factory setting is "Tube Position".)

(3) Press [Quit] key to exit the program. The confirmation message will appear. Press the appropriate key [Continue], [Set] or [Cancel].

Continue : To return to Work List setting screen so that setting can be continued.
Set : To save the new settings. Program ends.
Cancel : To cancel the new settings. Program ends.

7. OUTPUT SET VALUES

7.1 Output to GP

Use this program to print out a report of settings to a Graphic Printer.

To execute output settings:

(1) Press [Settings] key in the root menu.

(2) Press [Print Set Value] key in the second menu.

(3) The list of settings will be printed by the Graphic Printer.

NOTE:
- The "Password" is not printed.
- A settings report of 5 pages will be printed. The operator can not cancel printing halfway.

7.2 Backup to FD

Use this program to copy setting data to a floppy disk. The old data on a floppy disk will be replaced with the new data.

To execute backup settings:

(1) Press [Settings] key in the root menu.

(2) Press [Backup Set Value] key in the second menu. The Backup Setting Values window will appear.

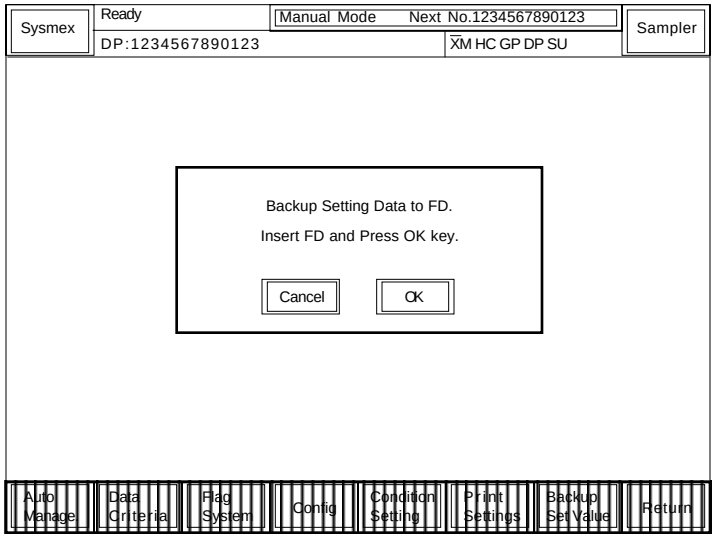


Figure 11-47: FD Backup Setting Window

(3) Insert the floppy disk into the drive.

(4) Press [Enter] to backup setting data onto the disk. While backup is in progress, the message "Backup..." will appear in the window.

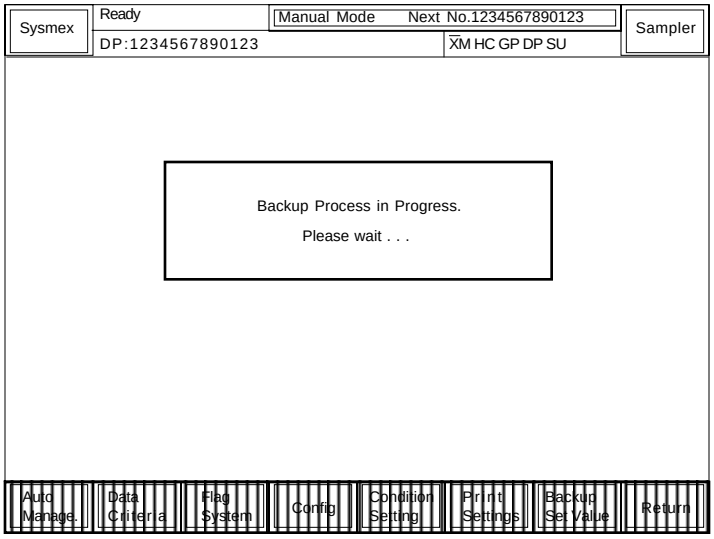


Figure 11-48: FD Writing Window

(5) If the settings cannot be written onto the floppy disk, the error message shown below will appear in the FD backup window. Insert the correct type of floppy disk and press [Enter].

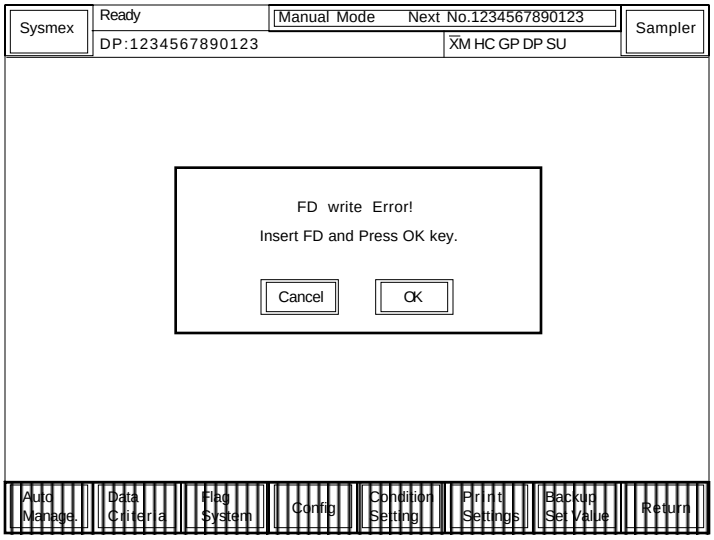
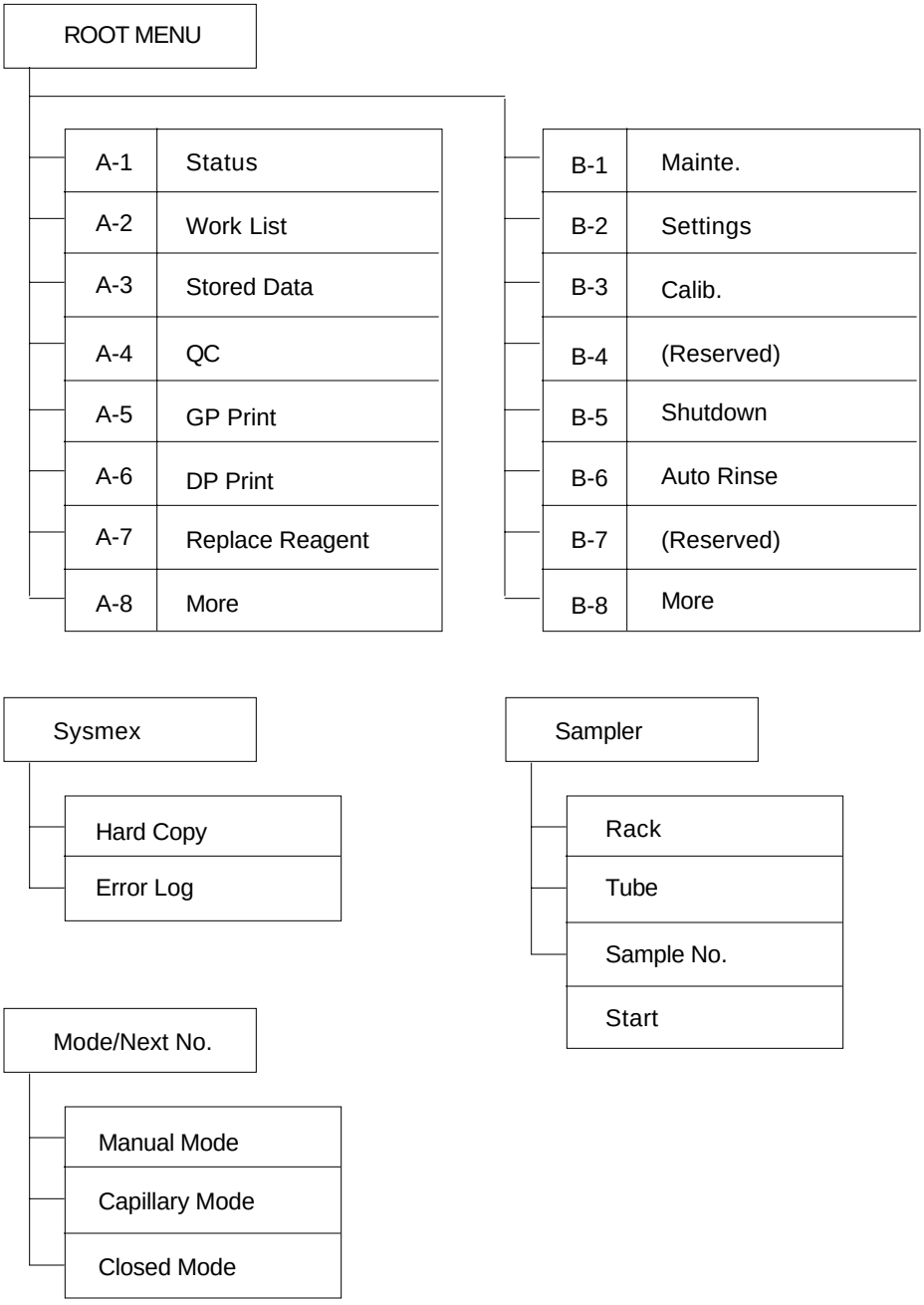


Figure 11-49: FD Write Error Message Window

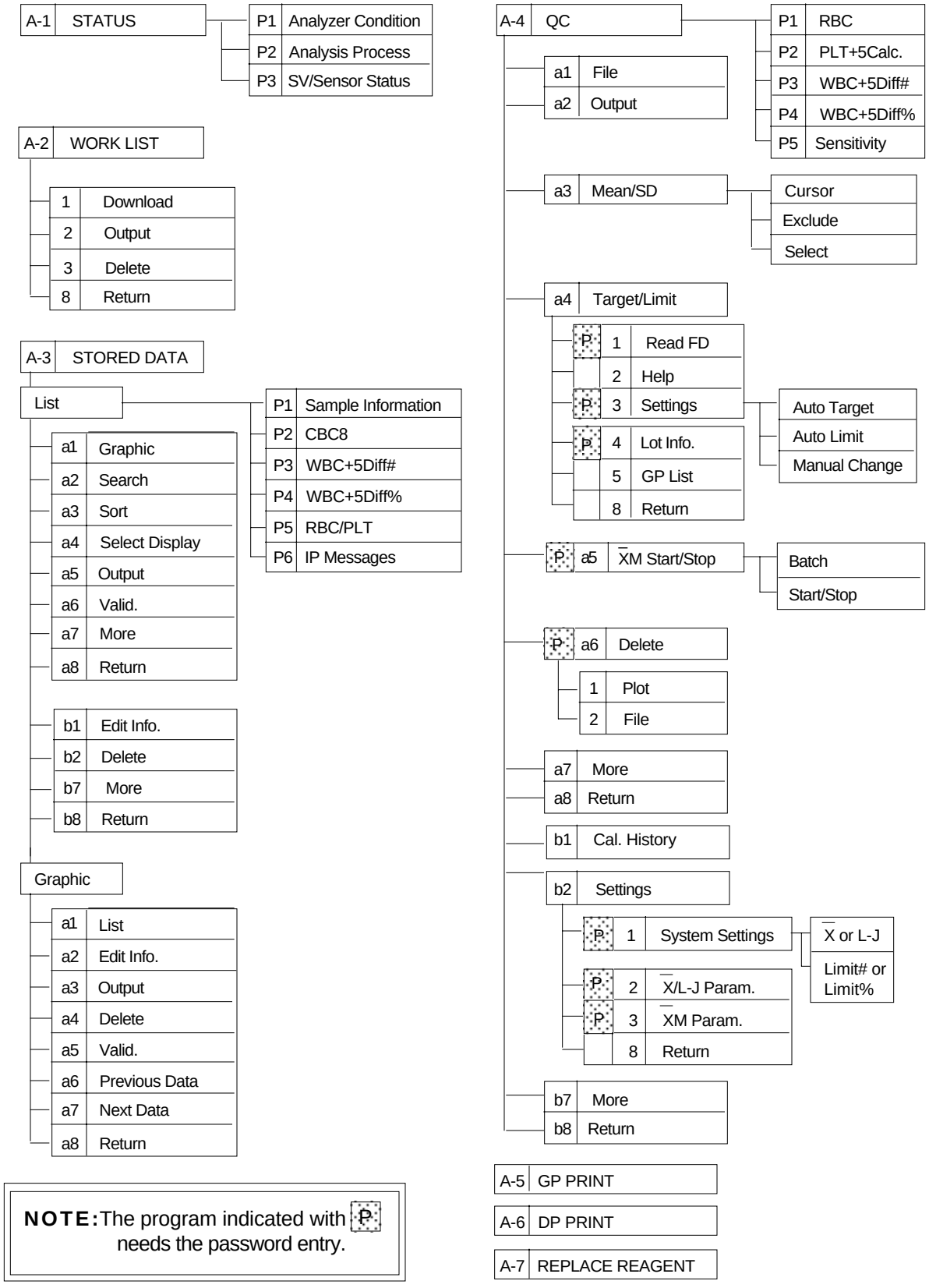
(6) Press [Cancel] to cancel processing and exit the program.

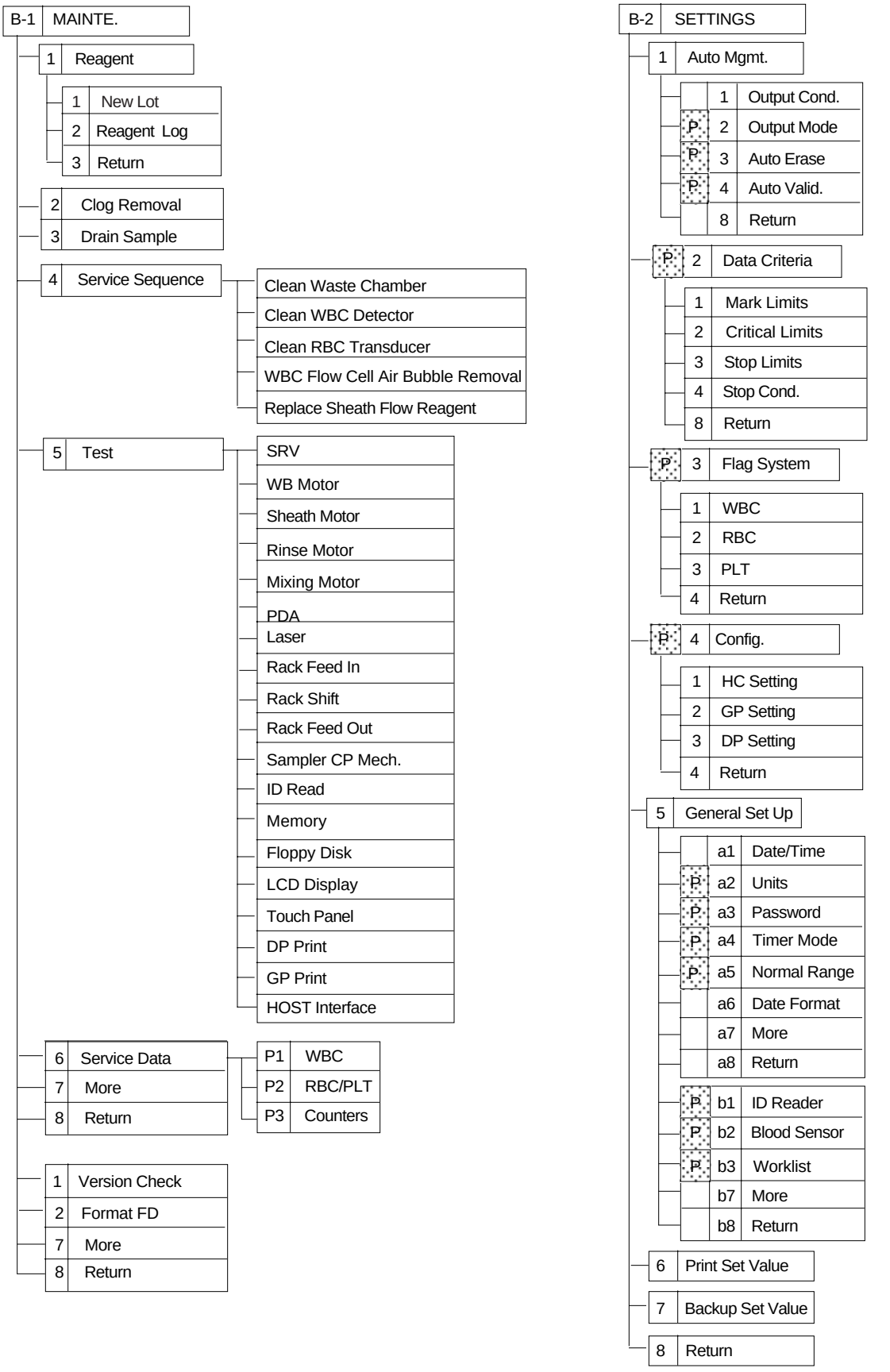
NOTE: Only the output of the setting values is possible. To restore the setting values, contact your Sysmex service representative.

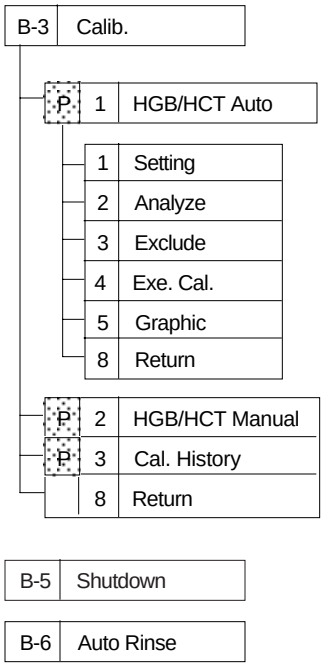
Appendix A: Menu Tree



(Refer to the following pages for the sub-programs of Root Menu.)


A-1 STATUS
P1 Analyzer Condition
P2 Analysis Process
P3 SV/Sensor Status
A-2 WORK LIST
1 Download
2 Output
3 Delete
8 Return
A-3 STORED DATA
List
P1 Sample Information
P2 CBC8
P3 WBC+5Diff#
P4 WBC+5Diff%
P5 RBC/PLT
P6 IP Messages
a1 Graphic
a2 Search
a3 Sort
a4 Select Display
a5 Output
a6 Valid.
a7 More
a8 Return
b1 Edit Info.
b2 Delete
b7 More
b8 Return
Graphic
a1 List
a2 Edit Info.
a3 Output
a4 Delete
a5 Valid.
a6 Previous Data
a7 Next Data
a8 Return
A-4 QC
P1 RBC
P2 PLT+5Calc.
P3 WBC+5Diff#
P4 WBC+5Diff%
P5 Sensitivity
a1 File
a2 Output
a3 Mean/SD
Cursor
Exclude
Select
a4 Target/Limit
P 1 Read FD
2 Help
P 3 Settings
P 4 Lot Info.
5 GP List
8 Return
Auto Target
Auto Limit
Manual Change
P a5 X̄M Start/Stop
Batch
Start/Stop
P a6 Delete
1 Plot
2 File
a7 More
a8 Return
b1 Cal. History
b2 Settings
P 1 System Settings
X̄ or L-J
Limit# or Limit%
P 2 X̄/L-J Param.
P 3 X̄M Param.
8 Return
b7 More
b8 Return
A-5 GP PRINT
A-6 DP PRINT
A-7 REPLACE REAGENT
NOTE: The program indicated with P needs the password entry.


B-1 MAINTE.
1 Reagent
1 New Lot
2 Reagent Log
3 Return
2 Clog Removal
3 Drain Sample
4 Service Sequence
Clean Waste Chamber
Clean WBC Detector
Clean RBC Transducer
WBC Flow Cell Air Bubble Removal
Replace Sheath Flow Reagent
5 Test
SRV
WB Motor
Sheath Motor
Rinse Motor
Mixing Motor
PDA
Laser
Rack Feed In
Rack Shift
Rack Feed Out
Sampler CP Mech.
ID Read
Memory
Floppy Disk
LCD Display
Touch Panel
DP Print
GP Print
HOST Interface
6 Service Data
7 More
8 Return
P1 WBC
P2 RBC/PLT
P3 Counters
1 Version Check
2 Format FD
7 More
8 Return
B-2 SETTINGS
1 Auto Mgmt.
1 Output Cond.
P 2 Output Mode
P 3 Auto Erase
P 4 Auto Valid.
8 Return
P 2 Data Criteria
1 Mark Limits
2 Critical Limits
3 Stop Limits
4 Stop Cond.
8 Return
P 3 Flag System
1 WBC
2 RBC
3 PLT
4 Return
P 4 Config.
1 HC Setting
2 GP Setting
3 DP Setting
4 Return
5 General Set Up
a1 Date/Time
P a2 Units
P a3 Password
P a4 Timer Mode
P a5 Normal Range
a6 Date Format
a7 More
a8 Return
P b1 ID Reader
P b2 Blood Sensor
P b3 Worklist
b7 More
b8 Return
6 Print Set Value
7 Backup Set Value
8 Return


B-3 Calib.
P 1 HGB/HCT Auto
1 Setting
2 Analyze
3 Exclude
4 Exe. Cal.
5 Graphic
8 Return
P 2 HGB/HCT Manual
P 3 Cal. History
8 Return
B-5 Shutdown
B-6 Auto Rinse

APPENDIX B: INSTALLATION

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    - 11.3 System Check B-32

1. PREINSTALLATION

In addition to verifying the proper power and environmental considerations outlined in *Chapter 1: Introduction*, the contents of the boxes shipped to the customer site must be verified prior to installation.

The SF-3000 system consists of the following units:

- Main Unit
- Pneumatic Unit
- Sampler Unit or Manual CP Unit (Optional)
- Bar Code Reader Unit (Optional)
- Graphic Printer or Line Printer (Optional)
- Data Printer (Optional)

Your Sysmex representative is responsible for unpacking, installing, and the initial set up of the SF-3000 system. The information in this section is given only for your completeness.

1.1 Unpacking Check List

Check the contents of each box to verify the following parts have been received:

(1) Main Unit Carton

Part No.	Description	Quantity		
		117 V	220 V	240 V
943-1912-4	SF-3000 Main Unit	1	---	---
943-1913-8	SF-3000 Main Unit	---	1	---
943-1914-1	SF-3000 Main Unit	---	---	1
943-2271-0	Air Drier No. 3 Assembly	1	1	1
462-2121-3	Awl	1	1	1
342-2626-4	Belt No.6	1	1	1
424-3733-7	Bottle Stand No.2-1 (Cream)	1	1	1
844-0122-8	Cubitainer Spout Kit CS-61 (C2)	2	2	2
943-1781-1	Cubitainer Spout Kit No. 1 (20 L)	1	1	1
462-2423-7	Cutting Pliers B-150 MM	1	1	1
362-8350-1	Decoration Seal No. 1	1	1	1
883-0192-3	Dispenser Kit No.1 (for 500 mL bottle)	2	2	2
363-1371-1	Fixing Metal No. 81	---	---	1
266-5011-3	Fuse 250V4A ST4-4A-N1 (N.Amer)	2	---	---
266-5106-0	Fuse 250V6.3A ST4-6.3A-N1 (N.A.)	1	---	---
266-5108-7	Fuse 250V8A ST4-8A-N1 (N.Amer)	2	---	---
266-5292-6	Fuse 250V2A No.19195 (Europe)	---	2	2
266-5293-0	Fuse 250V3.15A No. 19195 (Europe)	---	1	1
266-5297-4	Fuse 250V4A No.19195 (Europe)	---	2	2

(To Be Continued)

(1) Main Unit Carton (Continued)

Part No.	Description	Quantity		
		117 V	220 V	240 V
423-1776-2	Mini-Pette No. 10	2	2	2
343-2462-5	O-ring No.12	2	2	2
461-2459-3	Operator's Manual SF-3000	1	1	1
923-8092-8	Power Cord No.15 (C-2/N.Amer)	1	---	---
265-4719-0	Power Cord 4622-007-0092 (Europe)	---	1	---
265-4723-5	Power Cord F1686 (U.K.)	---	---	1
265-4708-9	Power Cord 6002+3020	1	---	---
265-4725-2	Power Cord 6002+3030	---	1	1
348-3812-1	Screw Binding M3 x 6 (SUS)	---	---	2
348-3926-8	Screw Binding M4 x 6 (SUS)	2	2	2
348-3933-4	Screw Binding M4 x 20 (SUS)	2	2	2
462-2381-8	Screwdriver Phillips No.1300#2	1	1	1
462-2391-5	Screwdriver Regular	1	1	1
346-6568-9	Seal No.18	1	1	1
345-5103-4	Spring 5-3	1	1	1
266-4461-8	Tie Wrap CV-100	10	10	10
462-2222-2	Tool No.2 (Orifice Cleaning Tool)	1	1	1
933-3601-9	Transducer Brush No.1	1	1	1
367-2800-6	Tray K-45H/SF-3K	1	1	1
367-1051-9	Tray No.20	1	1	1
442-5055-4	Tube Polyurethane 1.8mm x3.4mm	2 m	2 m	2 m
442-5338-7	Tube Polyurethane 4mmIDx6mmOD	15 m	15 m	15 m
442-5340-5	Tube Polyurethane 6mmIDx9mmOD	10 m	10 m	10 m
442-5292-3	Tube Silicone 1.5 mmID x 6 mmOD *	1 m	1 m	1 m
442-5301-0	Tube Silicone 3 mmID x 6.5 mmOD *	2 m	2 m	2 m
442-5290-6	Tube Silicone 4mmID x 8mmOD	20 cm	20 cm	20 cm
461-8726-9	Warranty Card	1	---	---
348-9502-9	Washer Flat M4 (SUS)	2	2	2
348-9502-9	Washer Flat M4 (SUS)	2	2	2

* These silicone tubes are used for the servicing purpose only.

(2) Pneumatic Unit Carton

Part No.	Description	Quantity		
		117 V	220 V	240 V
943-2962-4	Pneumatic Unit PU-14	1	---	---
943-2963-8	Pneumatic Unit PU-14	---	1	---
943-2964-1	Pneumatic Unit PU-14	---	---	1

(3) Sampler Unit Carton (Option)

Part No.	Description	Quantity
933-3634-1	CPSU-4 Main Unit Complete Assy	1
833-3315-1	Sample Rack (6 pieces/pack)	1
321-3067-0	Sampler Mounting Metal No.12 (with Ball Catcher)	2
348-3812-1	Screw Binding M3x6 (SUS)	4
368-9781-5	Spill Cover No. 37	1
368-0196-5	Anti-Shock Rubber No.49*	3
923-8101-4	Hand Clipper S#4 Assy (C-1/Pier)*	1
462-3530-2	Piercer Replacement Jig*	1
971-0591-5	Piercer Set No.3	1
368-0079-6	Rubber Plate No.39*	2
348-3926-8	Screw Binding M4X6 (SUS)*	1
348-9514-3	Washer Spring M4 (SUS)*	1

* These parts are included in the CPSU-4 Supply Part Box.

(4) Manual CP Unit Carton (Option)

Part No.	Description	Quantity
943-1111-7	KCP-4 Main Unit Complete Assy	1
322-3558-1	KCP-4 Front Dummy Cover	1
321-3067-0	Sampler Mounting Metal No.12 (with Ball Catcher)	1
348-3812-1	Screw Binding M3X6 (SUS)	2
348-3914-3	Screw Binding M3X10 (SUS)	1
348-3926-8	Screw Binding M4X6 (SUS)	1
348-9502-9	Washer Flat M4 (SUS)	1
368-0273-5	Rubber Cap No.33	1

(5) Bar Code Reader Unit Carton (Option)

Part No.	Description	Quantity
943-0501-8	BR-4 Assy	1
348-3812-1	Screw Binding M3X6 (SUS)	2

1.2 Supplementary Parts Information

When the Sampler Unit and/or Bar Code Reader is not installed for the SF-3000, the dummy cover and some parts to cover the opening are available. Also when the Manual CP Unit is installed, some parts are necessary to install the dummy cover.
Order the following items from your Sysmex Sales Representative, if needed.

(1) No optional unit is installed. (SF-3000 system only)

Part No.	Description	Quantity
951-1311-9	SF-3K Dummy Cover Assy	1

This assy includes Front Panel-C, ID Cover No. 1, Screw Binding M3X6 (SUS), Screw Binding M4X6 (SUS), Washer Spring M4 (SUS), Rubber Cap No.33 and Wiring Cord No. 1698.

(2) Only the Bar Code Reader is installed.

Part No.	Description	Quantity
322-3559-4	Front Panel-C	1
348-3812-1	Screw Binding M3X6 (SUS)	6
348-3926-8	Screw Binding M4X6 (SUS)	2
348-9514-3	Washer Spring M4 (SUS)	2
933-4441-1	Wiring Cord No. 1698	1
368-0273-5	Rubber Cap No.33	1

(3) Only the Sampler Unit is installed.

Part No.	Description	Quantity
322-3600-1	ID Cover No. 1	1
348-3812-1	Screw Binding M3X6 (SUS)	4
348-3926-8	Screw Binding M4X6 (SUS)	2
348-9514-3	Washer Spring M4 (SUS)	2
933-4441-1	Wiring Cord No. 1698	1

(4) Only the Manual CP Unit is installed.

Part No.	Description	Quantity
322-3600-1	ID Cover No. 1	1
348-3812-1	Screw Binding M3X6 (SUS)	8
348-3926-8	Screw Binding M4X6 (SUS)	1
348-9514-3	Washer Spring M4 (SUS)	1
943-2801-1	Wiring Cord No.1777	1
933-4441-1	Wiring Cord No. 1698	1

(5) When the Manual CP Unit and Bar Code Reader are installed.

Part No.	Description	Quantity
348-3812-1	Screw Binding M3X6 (SUS)	4
348-3926-8	Screw Binding M4X6 (SUS)	1
348-9514-3	Washer Spring M4 (SUS)	1
943-2801-1	Wiring Cord No.1777	1
933-4441-1	Wiring Cord No. 1698	1

2. LAYOUT AND WORK SPACE

Leave a space of at least 50 cm above and behind the instrument and at both sides. This is for convenience when servicing the instrument, and to allow for dissipation of heat from the instrument. The power outlets and drainage channel should be near the instrument. The power cords are 1.8 m long and the drain tube is 10 m long in the maximum. The Pneumatic Unit, reagents and printers should also be installed in convenient location.

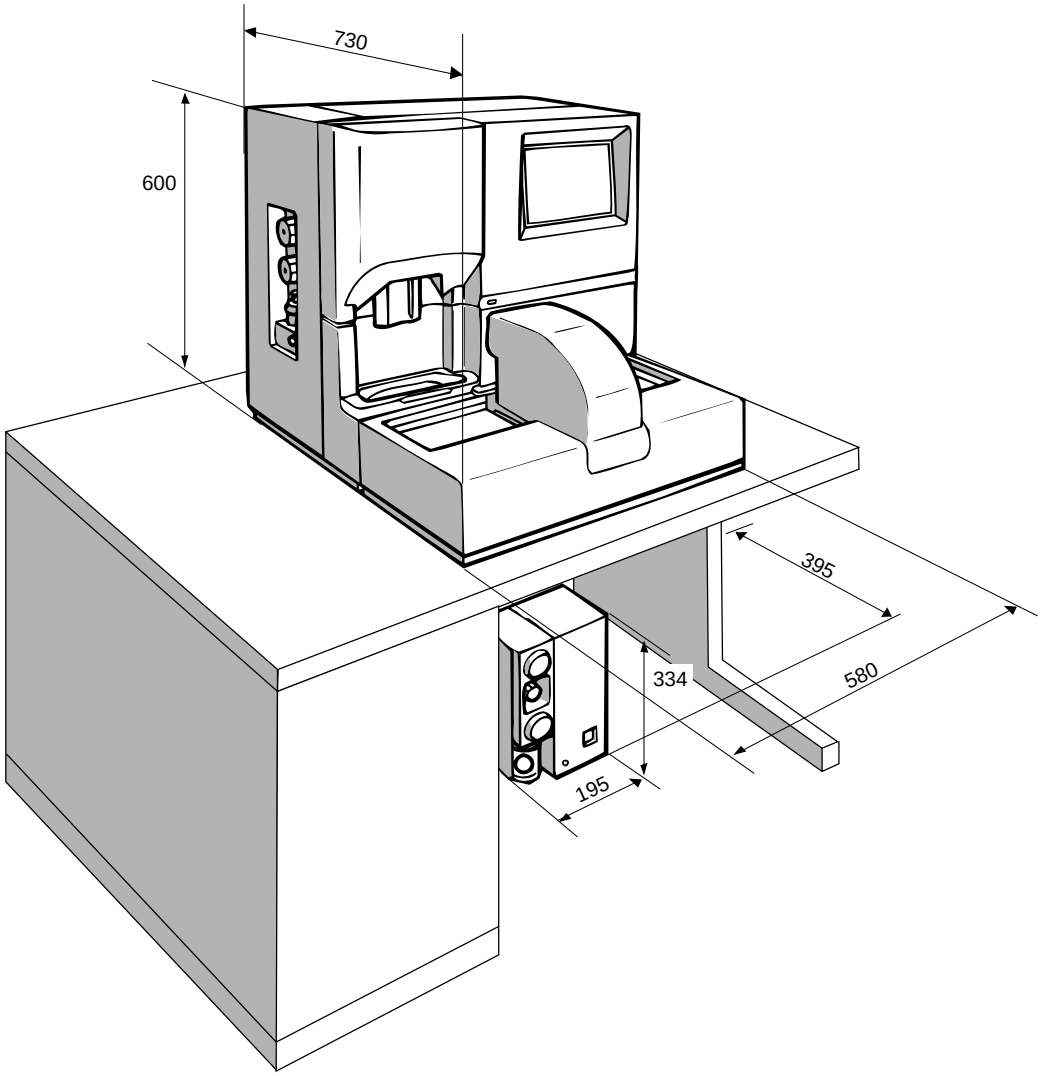

Figure B-1: Dimensions of System

3. REMOVING PACKING MATERIAL

3.1 Front Cover

Remove the tapes fastening the front cover.

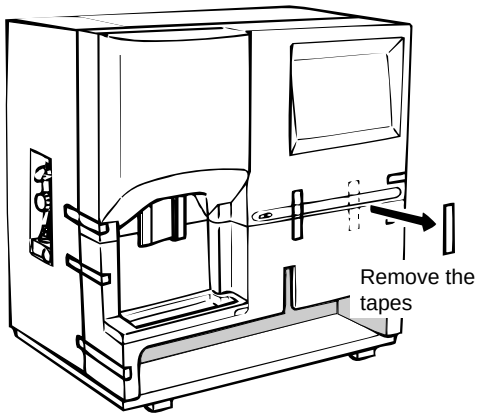

Figure B-2: Remove the Tapes

3.2 Front Panel

(1) Open the front cover.

> **WARNING!** When working with the front cover open, make sure that the stop bar is in place.

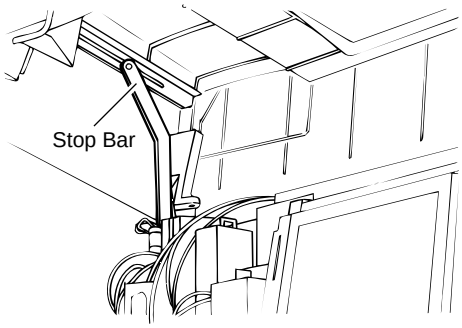

Figure B-3: Set Stop Bar

(2) Remove the screws fastening the front panel.

(3) Lift the front panel enough to release the hook under the panel (see Figure B-4).

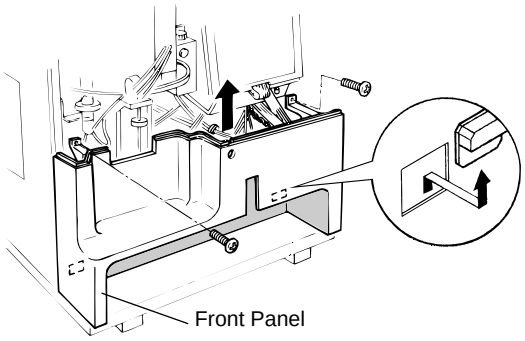

Figure B-4: Front Panel

NOTE:
- When installing the Sampler Unit and/or ID Reader, skip the steps (4) and (5) below.
- Order the cover(s) and some necessary parts if needed. *Refer to Section 1.2* in this chapter for dummy cover information.

(4) Install the ID reader dummy cover (ID Cover No. 1) with the three M3 screws to the front panel.
Install the sampler dummy cover (Front Panel-C) with the seven M3 screws.
Connect the grounding wire (Wiring Cord No. 1698) to the front panel using one M4 screw together with M4 washer spring. See Figure B-5.

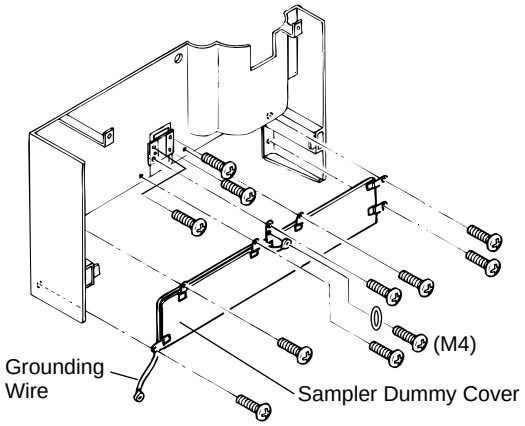

Figure B-5: Install the Dummy Cover(s)

(5) Connect the grounding wire and install the front panel to the Main Unit (see Figure B-6).

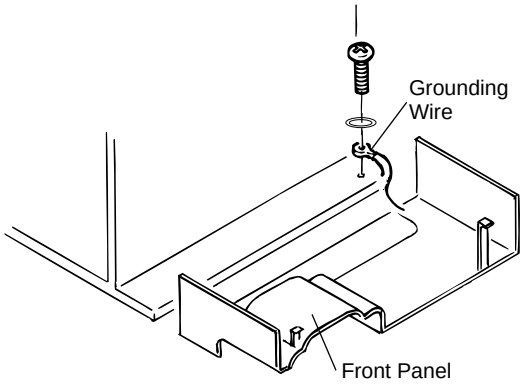

Figure B-6: Connect the Grounding Wire

(6) Install the Rubber Cap No.33 to the front panel.

3.3 Main Unit Chassis

Seal the holes of the sampler mounting rail attaching the screws to the Main Unit chassis with the supplied sealing tape (Decoration Seal No. 1).

NOTE:
- If you use the CP Sampler (option), do not seal the holes.
- If you use the Manual CP Unit (option), seal the left side hole only.

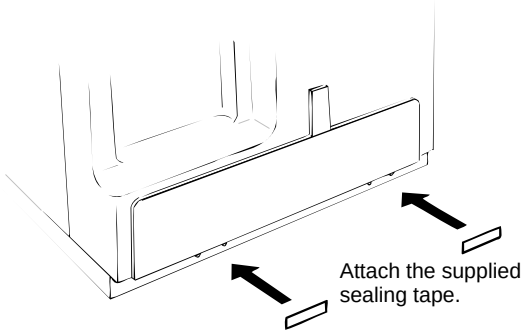

Figure B-7: Main Unit Chassis

3.4 SRV

(1) Remove the constant-pressure thumbscrew and disassemble the SRVs.

(2) Take out the Teflon protection sheets.

(3) Reinstall the constant-pressure thumbscrew and install the supplied SRV tray on the SRV.

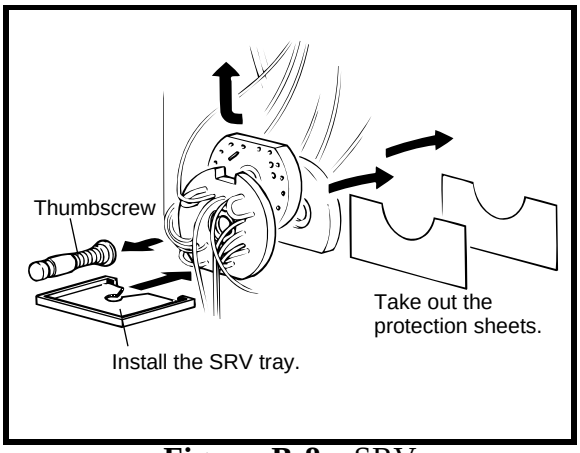

Figure B-8: SRV

CAUTION:
- Be careful not to damage the sampling valve surface; it may cause leaks.
- Do not bend the manual aspiration pipette when pulling out the valve.

3.5 Rear Panel

Remove the rubber caps protecting the reagent nipples.

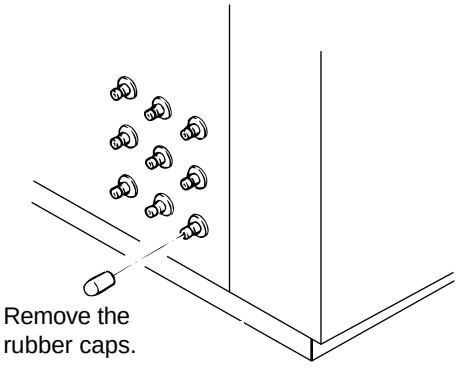

Figure B-9: Rear Panel

3.6 Pneumatic Unit

Remove the 2 screws fastening the compressor to the bottom plate of the Pneumatic Unit. Keep the screws in the parts box for future use.

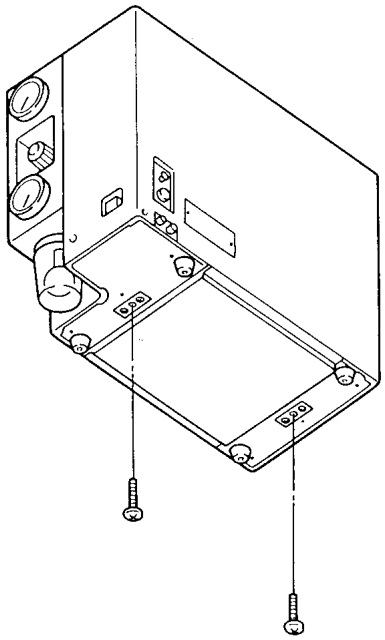

Figure B-10: Pneumatic Unit

4. TRAY

Install the supplied tray.

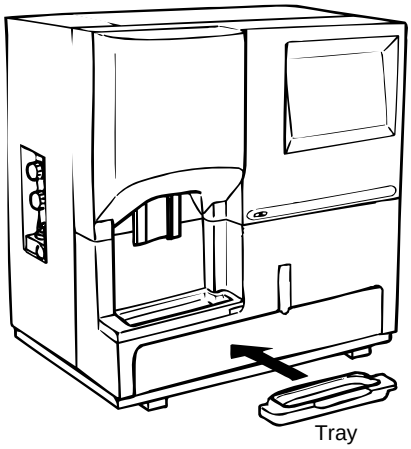

Figure B-11: Tray

5. BAR CODE ID READER (Optional)

NOTE: When using both the Sampler Unit and ID Reader, install the ID reader and then Sampler for easier installation.

NOTE: If the sampler (CPSU-4) installation is not required, install the sampler dummy cover with the grounding wire on the back of the front panel. Refer to *Section 3.3* in this chapter.

(1) Attach the ID Unit to the Main Unit chassis. Set the ID Unit stay on the protrusion of the Main Unit chassis and fix it using two screws.

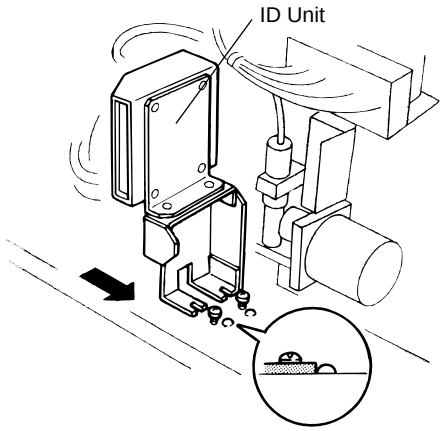

Figure B-12: Attach the ID Reader

(2) Pass the wire cord through the slit of ID Unit (see Figure B-13). Connect the wiring cord to the ID Unit.

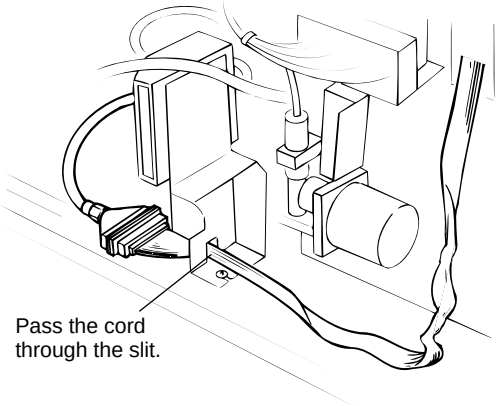

Figure B-13: Connect the Cord

6. CP SAMPLER UNIT (Optional)

6.1 Main Unit

> **NOTE:** If the ID reader installation is not required, install the ID reader dummy cover with the grounding wire on the back of the front panel. Refer to *Section 3.3* in this chapter.

(1) Remove the screws fastening the front panel.

(2) Lift the front panel a little to release the hook under the panel. See Figure B-14.

(3) Attach the sampler mounting metals (No. 12) to the Main Unit chassis. Lift the rail and press it against the bottom surface of the Main Unit chassis. See Figure B-15.

> **NOTE:** Make sure that there is no gap between the rail and the bottom surface of the Main Unit Chassis.

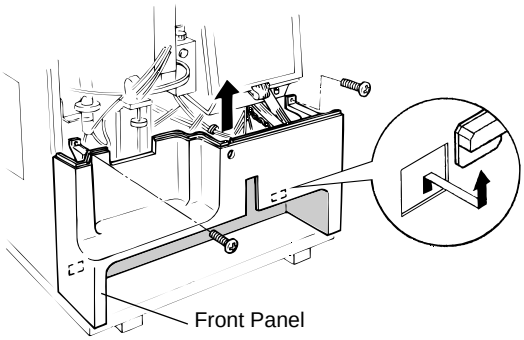

Figure B-14: Front Panel

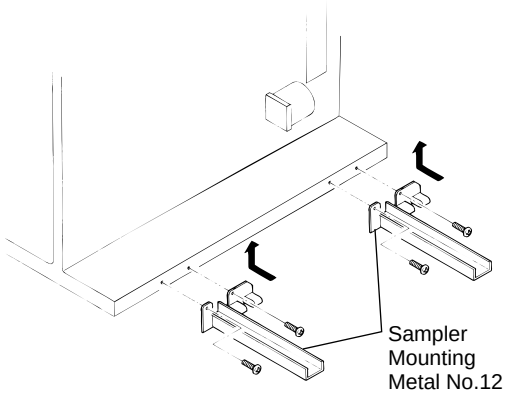

Figure B-15: Attach Sampler Mounting Metals

6.2 Sampler Unit

(1) Remove the tapes from the CP cover, then remove the CP cover.

(2) Remove the tapes holding the sampler table; then remove the sponges.

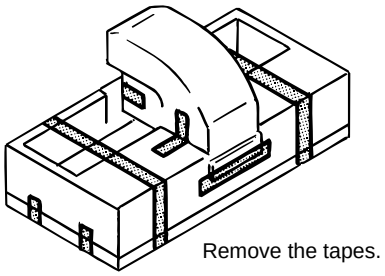

Figure B-16: Remove the Tapes

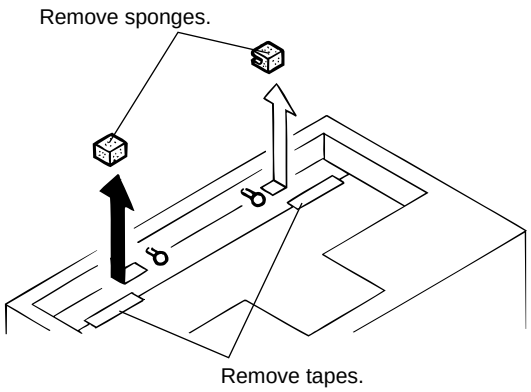

Figure B-17: Remove the Sponges

(3) Remove the mixer unit fixing plate by removing the 4 screws. Do not use these screws for re-mounting the hand clipper.

(4) Mount the hand clipper using the attached screws (M3 x 25).

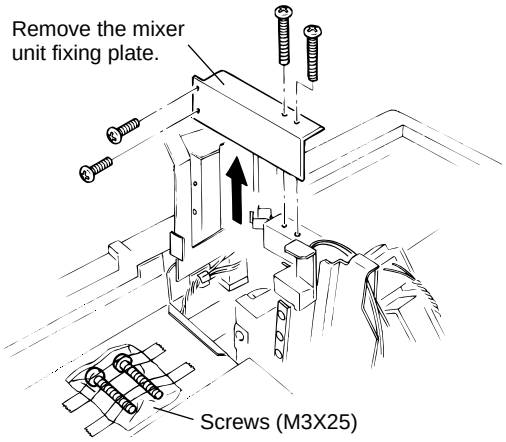

Figure B-18: Remove the Fixing Plate

6.3 Connection to Main Unit

(1) Using a screwdriver, remove the dummy cover from the fluid connector.

(2) Insert the sampler about halfway onto the sampler mounting rail.

(3) Connect the tubes and cables to the sampler connection unit at the bottom of the Main Unit (see Figure B-19).

Fluid connector 1
Silicone tube 1
Cord and cables 4
(Including ID Unit Cable)

When attaching the fluid connector, make sure to attach the rubber seal and align protrusions.

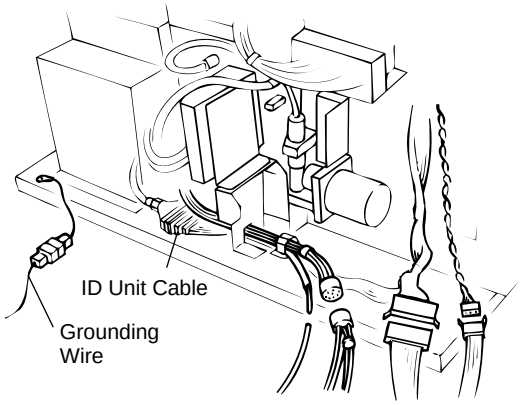

Figure B-19: Connect Tubes and Cables

CAUTION:
- When assembling the sampler, connect the ground cable (green/yellow cable) first.
- When disassembling the sampler, disconnect the ground cable last.

(4) Reinstall the Main Unit front panel.

(5) Push the sampler unit all the way toward the Main Unit. Make sure that the Sampler Unit is fixed securely with the catchers.

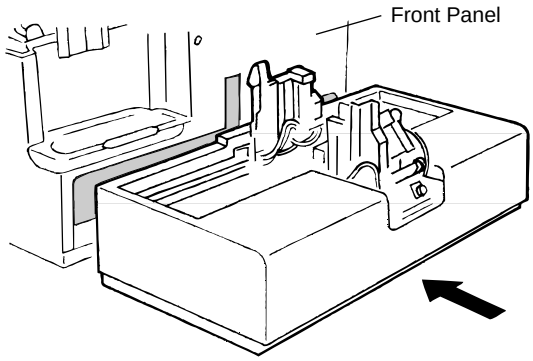

Figure B-20: Install the Sampler

(6) Connect the whole blood aspiration tube to the tube connection unit through the hole on the front panel as shown in Figure B-21.

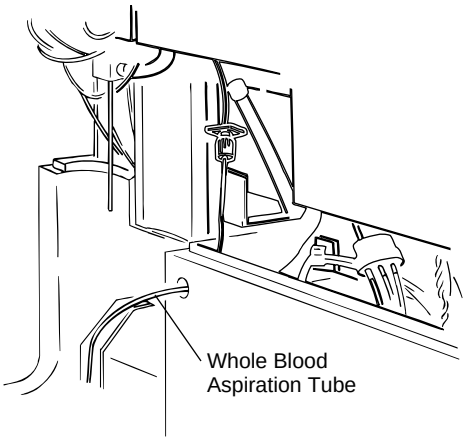

Figure B-21: Connect Whole Blood Aspiration Tube

(7) Install the sampler CP cover.

(8) Pass the whole blood aspiration tube through the guide in the cover.

7. MANUAL CP UNIT (Optional)

7.1 Main Unit

NOTE:
- When the Manual CP Unit is installed, the Wiring Cord No.1777 (P/N 943-2801-1) is necessary.
- When the Manual CP Unit is installed, the grounding wire and some screw bindings are necessary. Refer to *Section 1.2* and order the parts if needed.
- When the ID reader installation is not required, install the ID reader dummy cover with the grounding wire on the back of the front panel. Refer to *Section 3.2* in this chapter.

(1) Open the front cover and remove the front panel. See *Section 3: Remove Packing Material* in this chapter.

WARNING! When working with the front cover open, make sure that the stop bar is in place.

(2) Install the KCP-4 dummy cover using the M3x6 screws.

(3) Attach the grounding wire to the KCP-4 dummy cover with the M4 screw.

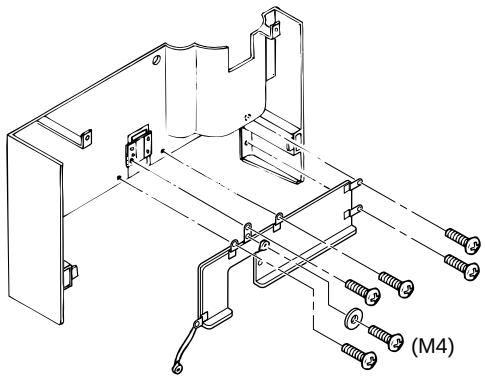

Figure B-22: Attach Grounding Wire

(4) Remove four fixing screws and open the LCD Unit. Then PCB No.1234 will appear.

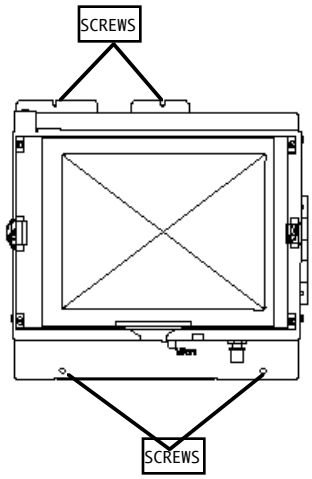

Figure B-23: Open LCD unit

(5) Connect the J1 and J2 of Wiring Cord No.1777 to the J11 and J13 on PCB No.1234 respectively.

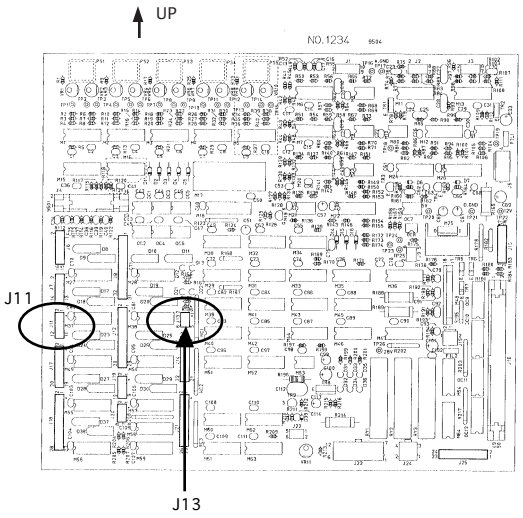

Figure B-23-1: PCB No.1234

(6) Close the LCD Unit and fix it by four screws.

7.2 Manual CP Unit

Remove the cover from the Manual CP Unit.

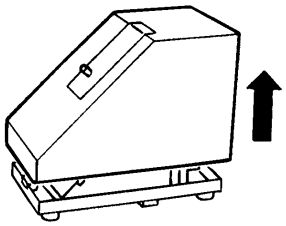

Figure B-24: Remove Manual CP Unit Cover

7.3 Connection to Main Unit

(1) Disconnect the grounding wire connector of Manual CP unit. Use a screw to attach this wire and the grounding wire of MCP dummy cover together to the Main Unit Chassis. See the figure below.

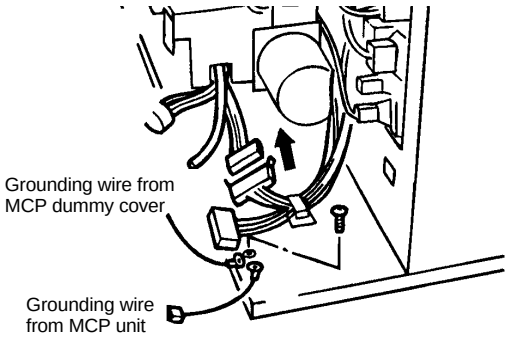

Figure B-25: Connect Grounding Wires

(2) Reinstall the front panel on the Main Unit.

(3) Attach the sampler mounting metals to the Main Unit chassis. See the figure below.

> **NOTE:** To install the sampler mounting metal to the Main Unit Chassis, lift the rail and press it against the bottom surface of the Main Unit chassis.

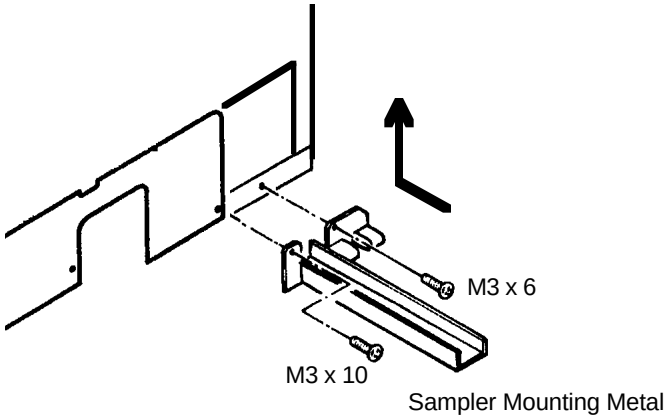

Figure B-26: Attach Sampler Mounting Metals

(4) Use a screwdriver to remove the dummy cover from the fluid connector.

(5) Insert the Manual CP unit halfway onto the mounting rail.

(6) Connect the tubes and cables to the Main Unit (see Figure B-27) except the whole blood aspiration tube.

(7) Fasten the fluid connector and make sure to attach the rubber seal and align protrusions.

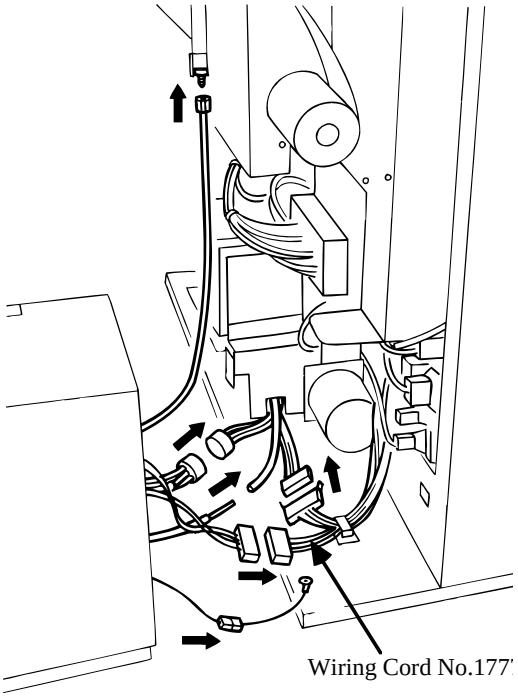

Figure B-27: Connect Tubes

CAUTION:
- When assembling the sampler, connect the ground cable (green/yellow cable) first.
- When disassembling the sampler, disconnect the ground cable last.

(8) Push the Manual CP unit all the way toward the Main Unit and make sure that the MCP Unit is fastened securely with the catchers.

(9) Fasten the Manual CP Unit to the Main Unit Chassis with the screw binding (see Figure B-28).

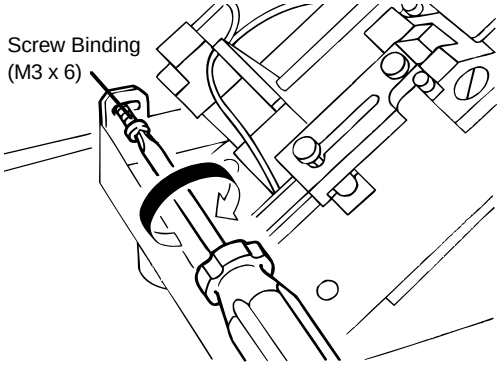

Figure B-28: Install Manual CP Unit

(10) Connect the whole blood aspiration tube in place (see Figure B-29).

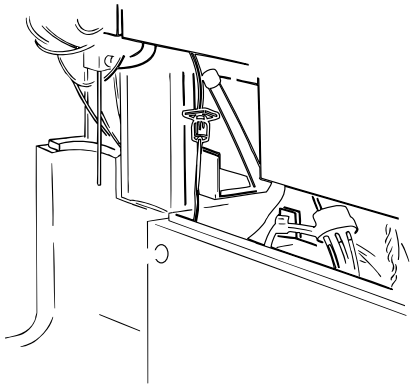

Figure B-29: Connect Whole Blood Aspiration Tube

(11) Connect the Rubber Cap No.33 to the front panel.

NOTE:	For use of SARSTEDT collection tube, please order and prepare Piercer SE-M SA (PM) (P/N 921-0776-2).

(12) Close the MCP cover.

(13) After installation completes, verify that blood aspiration is performed without any problem.

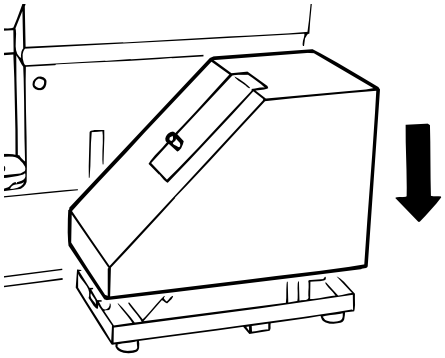

Figure B-30: Close MCP Cover

8. TUBE CONNECTION

8.1 Vacuum Line

Connect the Pneumatic Unit, vacuum outlet nipple (marked VACUUM and a blue label) and Main Unit vacuum inlet nipple (marked VACUUM) using the polyurethane tube (4 mmID x 6 mmOD) provided.

8.2 Pressure Line

(1) Install the air drier to the rear panel (see Figure B-31). Fit the air drier, and secure it using the provided binding screws M4 and flat washers M4.

(2) Connect the Pneumatic Unit pressure outlet nipple (marked PRESSURE and a red label) to the air drier inlet nipple using the provided polyurethane tube (4 mmID x 6 mmOD).

(3) Connect the instrument pressure inlet nipple (marked PRESSURE) to the air drier outlet nipple using the provided polyurethane tube (4 mmID x 6 mmOD).

(4) Connect the air drier drain outlet nipple at the bottom of air drier to the drain inlet nipple using the provided polyurethane tube (1.8 mmID x 3.4 mmOD).

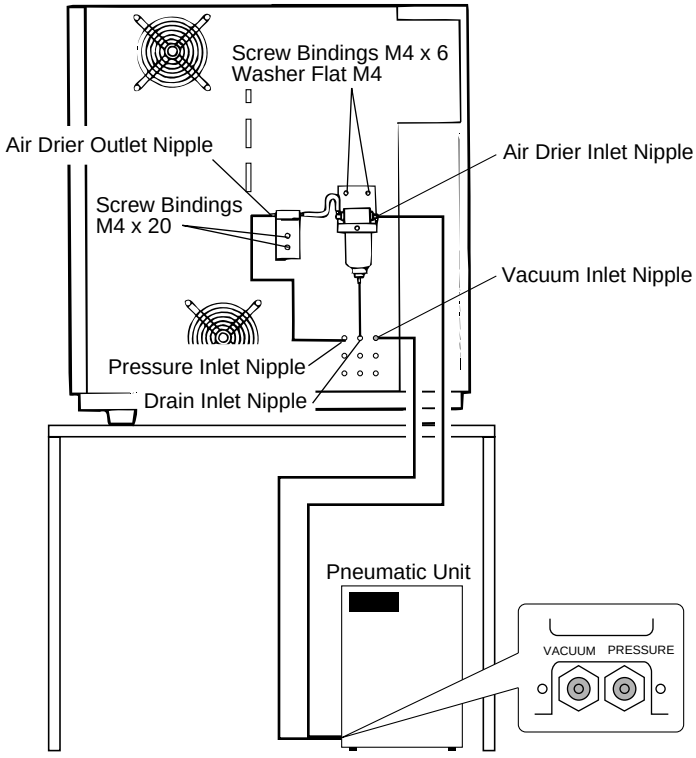

Figure B-31: Pneumatic Tube Connections

8.3 Reagent Container Preparation

Follow the procedure below to install the Cubitainer Spout Kit and Dispenser Kit to the reagent containers. Refer to this table for the abbreviated names and brand names of reagents, and connection methods.

Table B-1: Reagents, Color marker and Connection Method

Abbreviation	Brand Name	Volume	Connection Method
PK	CELLPACK	20 L	Cubitainer Spout Kit No. 1
FBA	STROMATOLYSER-FB	5 L	Cubitainer Spout Kit CS-61
FDO	STROMATOLYSER-FD (I)	5 L	Cubitainer Spout Kit CS-61
FDT	STROMATOLYSER-FD (II)	500 mL	Dispenser Kit No. 1
SLS	SULFOLYSER	500 mL	Dispenser Kit No. 1

1. Dispenser Kit No. 1

(1) Detach the labels SLS and FDT from the provided Indication Mark No. 908 (shown in Figure B-32).

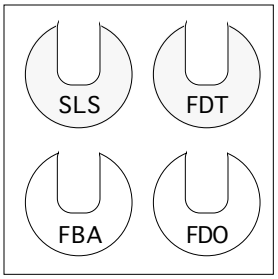

Figure B-32: Indication Mark No. 908

(2) Attach them on the cap of the Dispenser Kit No. 1 as shown in Figure B-33. These labels will help identify the proper tube connection when the reagent is replaced.

- Attach the Indication Mark "FDT" to the cap of the Dispenser Kit No. 1 for STROMATOLYSER-FD (II).
- Attach the Indication Mark "SLS" to the cap of the Dispenser Kit No. 1 for SULFOLYSER.

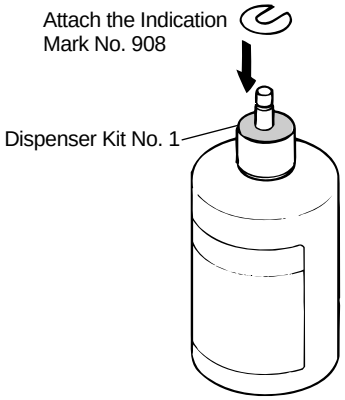

Figure B-33: Attach the Label

2. Assemble Cubitainer Spout Kit No.1

(1) Rinse the assembled silicone tube and weight in the reagent from the container. This is to prevent the tube and weight from contaminating the reagent cube.

(2) Insert the Cubitainer Spout Kit into the container and screw down the cap. Keep the container cap in a safe place for future reuse.

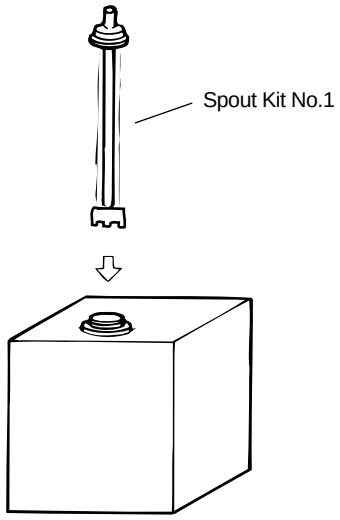

Figure B-34: Assemble Cubitainer Spout Kit No. 1

CAUTION: Verify that the Cubitainer Spout Kit No.1 stands vertically in the Cubitainer.

3. Assemble Cubitainer Spout Kit CS-61

(1) Detach the labels FBA and FDO from the provided Indication Mark No. 908 (shown in Figure B-35).

(2) Attach them on the connector of each Cubitainer Spout Kit. These labels will help identify the proper tube connection when the reagent is replaced.

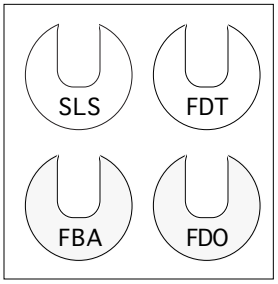

Figure B-35: Indication Mark No. 908

- Attach the Indication Mark "FBA" to the cap of the Spout Kit for STROMATOLYSER-FB.
- Attach the Indication Mark "FDO" to the cap of the Spout Kit for STROMATOLYSER-FD (I).

> **CAUTION:** Do not cover the hole on the Spout Kit cap with the label.

(3) Cut the silicone tube provided in the kit so that there will be a 2.5 cm clearance between the tube end and the bottom of the container.

(4) Assemble the parts of the Cubitainer Spout Kit.

(5) Rinse the assembled silicone tube and weight in the reagent with which they will be used. This is to prevent the tube and weight from contaminating the reagent cube.

(6) Insert the Cubitainer Spout Kit into the container and screw down the cap. Keep the container cap in a safe place for future reuse.

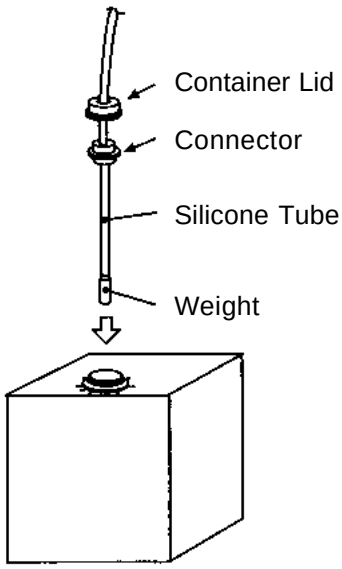

Figure B-36: Assemble Cubitainer Spout Kit CS-61

8.4 Reagent Lines

(1) Prepare the following reagent tubes:

- Tube polyurethane 4 mmID x 6 mmOD --- 5
- Tube silicone 4 mmID x 8 mmOD --- 2 (for 500 mL bottles of FDT and SLS)

(2) Connect the reagent inlet nipples to the reagent containers using the polyurethane tube (4 mmID x 6 mmOD). Use two each of silicone tube (4 mmID x 8 mmOD) when connecting the 500 mL bottles. See the figure below.

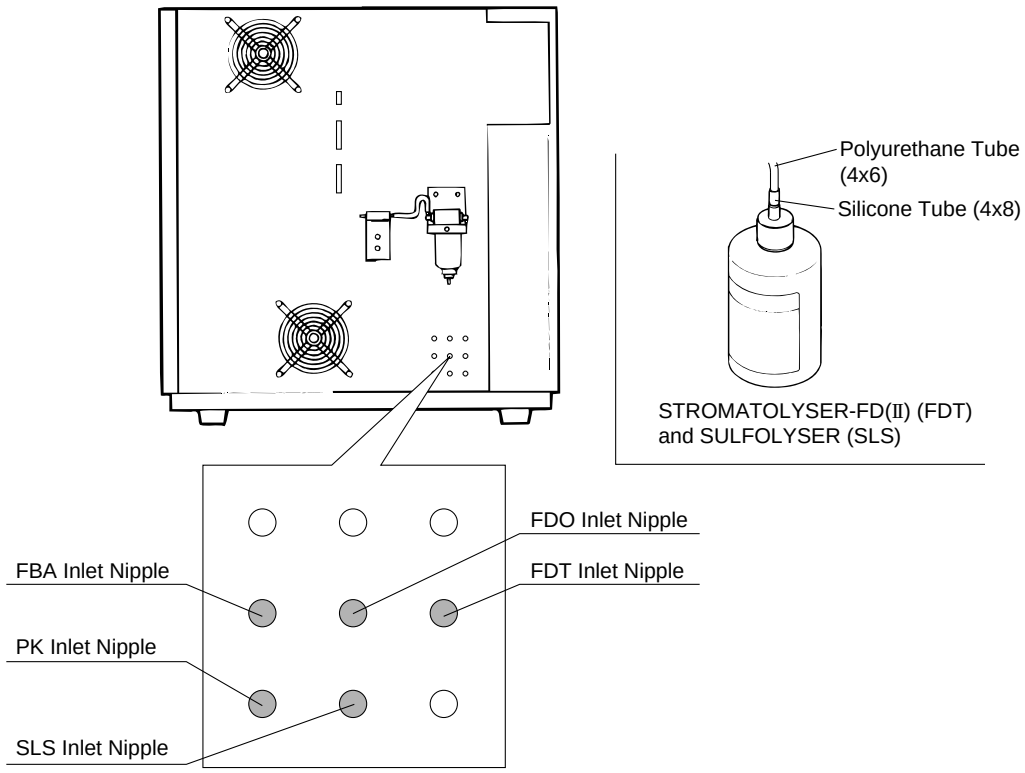

Figure B-37: Reagent Connections

CAUTION:
- Do not spill reagent onto the instrument. If reagent does spill, wipe out immediately with a damp cloth.
- If reagent gets on clothes or skin, wash immediately with excess water. If reagent gets into eyes, flush with water and seek medical attention immediately.
- Store reagent between of 5 - 30˚C. (Do not let reagent freeze.)
- Do not let dirt, dust, or germs get into the reagent after it has been opened. Reagent must be used within two months of opening.

8.5 Waste Container

Connect one end of the polyurethane tube provided (6 mm ID x 9 mm OD) to the instrument waste outlet nipple (marked WASTE). Connect the other end to the waste sewer or waste container.

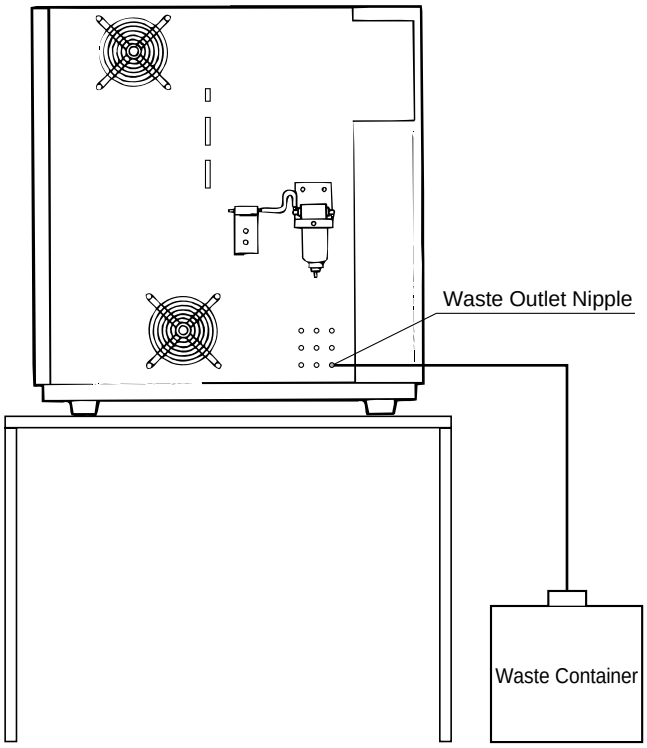

Figure B-38: Waste Tube Connection

CAUTION: Position the waste sewer or waste container lower than the instrument waste nipple. The length of the waste tube should not exceed ten meters (10 m).

9. BATTERY BACKUP

(1) Loosen the 2 screws at the front of the right side panel. Remove the right side panel by sliding it backward as shown in Figure B-39.

(2) Pull out the PCB No. 6358. See Figure B-40.

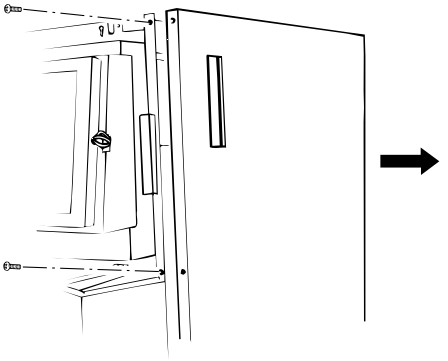

Figure B-39: Loosen Screws

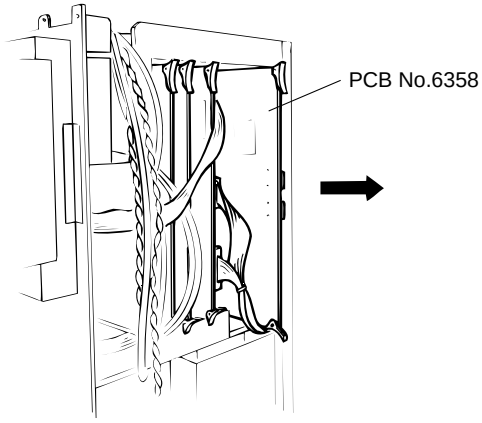

Figure B-40: Remove PCB No. 6358

(3) Connect the battery connector to the J11 of PCB No. 6358 as shown in Figure B-41.

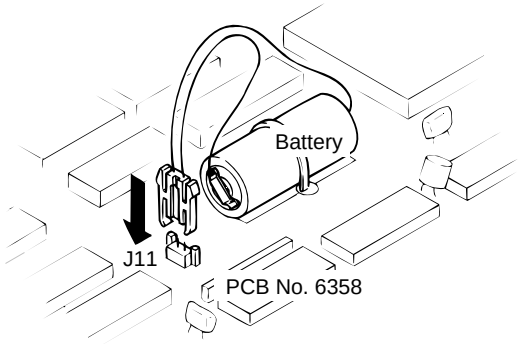

Figure B-41: Connect Battery Connector

(4) Install the PCB No. 6358.

(5) Install the right side panel, and secure it with two screws.

10. CABLE AND POWER CORD CONNECTIONS

10.1 Output Connections

Connect the host computer and/or printers to the appropriate interfaces on the Main Unit.

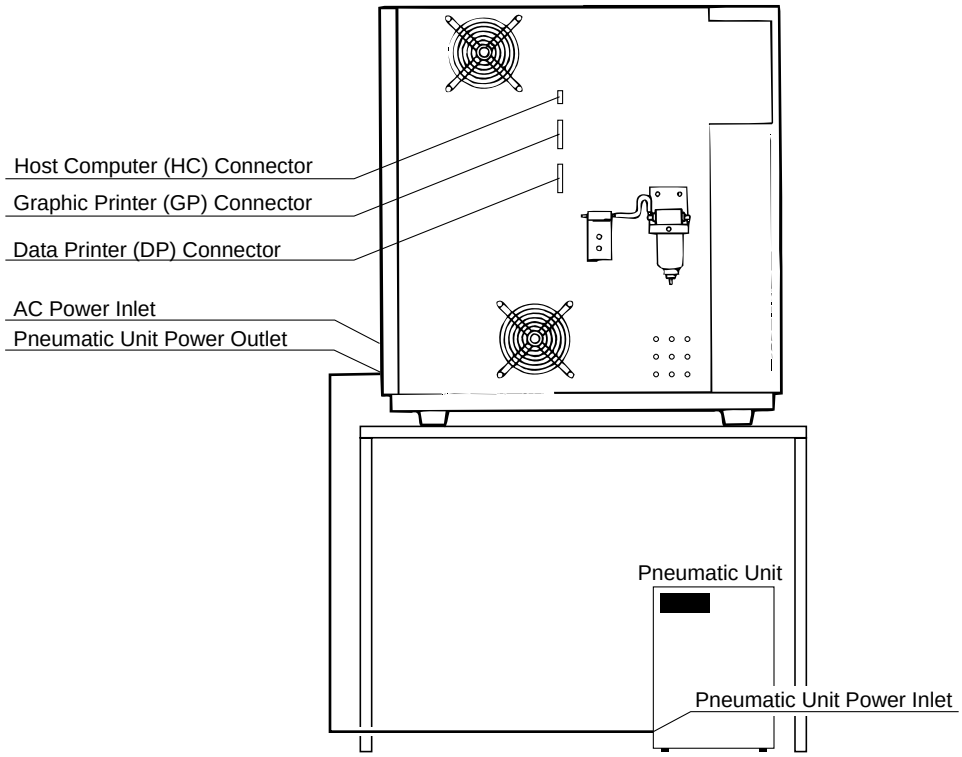

Figure B-42: Cable and Power Cord Connections

NOTE:
- If a Data Printer is to be connected to the SF-3000, a separate "CABLE PRINTER C-11 (DP/GP/J-3100)"(P/N 265-7660-9) is required.
- If a user-supplied graphic printer is to be connected to the SF-3000, a "CABLE PRINTER C-11 (DP/GP/J-3100)"(P/N 265-7660-9) is required.

10.2 Pneumatic Cable Connections

Connect the Pneumatic Unit power connector to the pneumatic power outlet on the Main Unit using the power cord provided in the supply part.

CAUTION: *Requirement by the British Electrical Safety Standards* -- On the 240 VAC specification instrument, fix the pneumatic power cord with a fixing metal using 2 fixing screws (M3x6) to prevent accidental disconnection of the pneumatic power cord. See Figure B-43 below.

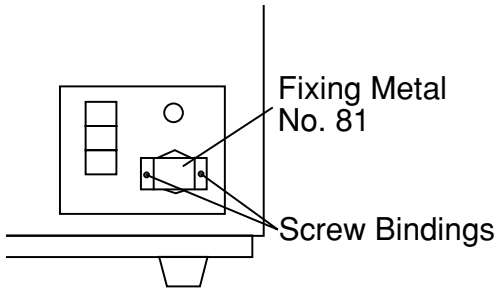

Figure B-43: Installing Fixing Metal No. 81

10.3 Power Cord Connections

Connect the Main Unit power connector to the AC power outlet using the power cord provided in the supply part.

11. POWER ON AND SYSTEM SETUP

The following procedures should be done by your Sysmex service representative at the time of installation. The outline of each procedures are described below for your reference.

11.1 Power On

(1) Connect the Main Unit power connector to the AC power outlet using the power cord provided in the supply part.

(2) Turn ON the power to the Main Unit and start up the instrument in the Hot Start mode. Perform "Format BBU".

(3) Turn OFF the power to the Main Unit.

(4) Turn ON the power of the printer(s) and/or host computer, if installed.

(5) Turn ON the power of the Pneumatic Unit, and then Main Unit. Start up the instrument in the Hot Start mode. Skip the Auto Rinse.

CAUTION:
When the Rinse Mechanism comes out from the Whole Blood Aspiration Pipette completely, insert the pipette into the Rinse Mechanism hole by hands referring to the Figure B-44.

If not inserted properly, "Rinse Motor Function Error" may occur when turning the power ON.

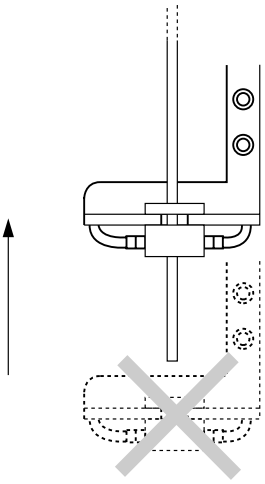

Figure B-44: Rinse Mechanism Position

11.2 System Setup

(1) When the instrument changes to the READY status, set "Time/Date". Refer to *Chapter 11: System Setup*.

(2) When an optional host computer and/or printer(s) is used, refer to *Chapter 11: System Setup* for the connection and configuration.

(3) When an optional Sampler Unit/Manual CP Unit and/or ID Bar Code Reader is used for the SF-3000, change the software DIP switch settings.

(4) Prime the hydraulic lines.

11.3 System Check

- **Verify Pressure and Vacuum**

(1) When the system becomes "Ready", press the [Status] key and then [→] key.

(2) Pressure and vacuum values are displayed. Verify that these pressure and vacuum readings are within the acceptable limits.

- **Extended Background Check**

(1) When the system becomes "Ready", enter the Service Mode.

(2) Set the instrument in the Continuous Operation Mode. The system automatically starts continuous blank analysis.

(3) Stop the Continuous Operation Mode when the background values are less than or equal to those shown in the table below.

Table B-2: Acceptable Background Limits

Parameters	Acceptable Limits
WBC/BASO Channel	0.1 [x 10^3/µL]
DIFF Channel	0.1 [x 10^3/µL]
RBC	0.02 [x 10^6/µL]
HGB	0.1 [g/dL]
PLT	10 [x 10^3/µL]

- **Verify HGB Blank Level**

(1) When the system becomes "Ready" and 30 minutes have been passed after turning ON the power, press the [Status] key and then [→] key.

(2) HGB Blank value is displayed. Verify that this HGB blank value is within the acceptable range.

- **Clean WBC Detector and Remove Air Bubbles in WBC Flow Cell**

(1) Press the [Mainte.] key and then [Service Sequence] key.

(2) Run the WBC Detector cleaning sequence by pressing the [Clean WBC Detector]. Refer to *Chapter 5, Section 4.2: Execute Clean WBC Detector Sequence.*

(3) Run the WBC Flow Cell air bubble removal sequence by pressing the [WBC Flow Cell Air Bubble Removal]. Refer to *Chapter 5, Section 7.5: Execute WBC Flow Cell Air Bubbles Removal Sequence.*

- **Optical Alignment Check**

(1) Analyze the material for laser adjustment in the Manual mode.

(2) Verify that the scattergram shows small group of the particles. If it shows abnormally enlarged groups of particles, clean the WBC Detector by executing the cleaning sequences. Refer to *Chapter 5: Maintenance* for the procedures.

(3) Press [Mainte.] key in the root menu. Bring the WBC Service Data by pressing [Service Data] from the maintenance submenu.

(4) Verify that the WBC/BASO-X (W), WBC/BASO-Y (W), DIFF-X (W) and DIFF-Y (W) results fall within the acceptable range. If a parameter falls outside the range, adjust the optical axis.

- **Sensitivity Check**

(1) WBC Sensitivity:
Analyze the SF-CHECK (Normal Level). Verify that the WBC/BASO-X, WBC/BASO-Y, GRAN-X and GRAN-Y in the WBC Service Data fall within the acceptable range. If a parameter falls outside the range, adjust the WBC sensitivity.

(2) RBC Sensitivity:
Analyze the CELLCHECK-400. Verify that the MCV data falls within the acceptable range. If it falls outside the range, adjust the RBC sensitivity.

(3) PLT Sensitivity:
Analyze the PLT reference material. Verify that the P-MFV data falls within the acceptable range. If it falls outside the range, adjust the PLT sensitivity.

- **Accuracy**

Analyze the SF-CHECK five times in the Manual mode. Verify that the average of the five results falls within 2SD of the assayed target value.

- **Mode-to-Mode Calibration**

(1) When a CP Sampler Unit is installed, analyze 10 normal fresh patient samples both in the Open Manual mode and the Closed Sampler mode.

(2) Calculate the mean of those samples in the Open Manual mode and the mean of those samples in the Closed Sampler mode. Verify that either the percent difference or the absolute difference value is within the following specification.

Specification:

WBC:	within ±5%, or within ±0.40 x 10^3/µL
RBC:	within ±2%, or within ±0.02 x 10^6/µL
HGB:	within ±2%, or within ±0.2 g/dL
HCT:	within ±2%, or within ±0.3 Hct%
PLT:	within ±7%, or within ±20 x 10^3/µL
NEUT%:	within ±5.0 NEUT%
LYMPH%:	within ±4.0 LYMPH%
MONO%:	within ±3.0 MONO%
EO%:	within ±2.0 EO%
BASO%:	within ±1.0 BASO%

(3) If not found within the specification, obtain and set the calibration value.

- **ID Reader**

NOTE: When adjusting the ID Bar-Code Reader, contact your Sysmex service representative for his/her instruction and assistance.

(1) Pull out the Sampler Unit by approx. 10 cm, and remove the Main Unit Front Panel-B Assy.

CAUTION:
- DO NOT open the front panel or try to remove the Sampler Unit without instruction and assistance of Sysmex service representative.
- DO NOT pull the Sampler Unit more than 10 cm to avoid tubing disconnection.

(2) Push and refit the Sampler Unit.

CAUTION: When refit the Sampler Unit, take care not to pinch the tubing.

(3) Prepare the sample racks containing blood collection tubes with the 2 mm wide ID bar-code labels attached properly. See Figure B-45.

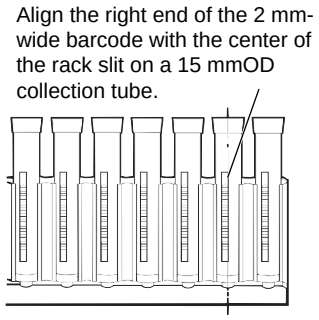

Figure B-45: Affixing the Bar-Code Labels

(4) Perform the ID reader test program by pressing [Mainte.], [Test] and [ID Read] keypads. When "Set Rack and press Start Switch" appears, press the Start Switch. (Refer to *Chapter 8, Section 3.7: Test Bar Code Reader* for the procedures.)

(5) Verify that the ID bar-codes are read correctly.

(6) If the bar-code reading failed, adjust the position of the ID Reader.
Loosen the fixing screws A and B shown in Figure B-46, and move the ID Reader screw B side while fixing the screw A position.

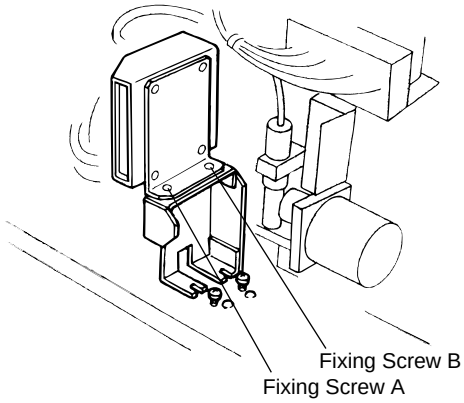

Figure B-46: Adjusting the Bar-Code Reader Position

(7) Repeat the ID read test program to verify the bar-codes are read correctly.

(8) When the adjustment is complete, pull out the Sampler Unit by approx. 10 cm, and refit the Front Panel-B Assy.

(9) Refit the Sampler Unit.

CAUTION: When refit the Sampler Unit, take care not to pinch the tubing.

APPENDIX C: TECHNICAL INFORMATION

The following technical information has been included for your reference.

1. SERIAL INTERFACE FOR HOST COMPUTER..... C-2
- 1.1 Connection C-2
- 1.2 Input/Output Signals C-2
- 1.3 Communication Format..... C-2
- 1.4 Baud Rate/Character Structure C-2
- 1.5 Signal Level C-3
- 1.6 Interface Circuit..... C-3
- 1.7 Software C-4

2. TEXT FORMAT..... C-8
- 2.1 Patient Sample Data Format C-8
- 2.2 Quality Control Data Format C-12
- 2.3 Inquiry Data Format.....C-14
- 2.4 Order Information Data Format C-15

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- 3.1 Applicable Bar Codes C-17
- 3.2 Dimensions of Elements C-18
- 3.3 Requirements on Wide/Narrow Ratio.....C-18
- 3.4 Optical Requirements.....C-18
- 3.5 Dimensions of Bar Code Label C-20
- 3.6 Check-Digit.....C-20
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- 3.8 Effective Bar Code Length C-28

1. SERIAL INTERFACE FOR HOST COMPUTER

A serial interface is available on the Main Unit rear panel for connecting to a host computer. The bit serial voltage type, which conforms to the RS-232C interface, is used for input and output to and from the SF-3000.

1.1 Connection

Connect an EIA RS-232C V.24 standard 9-pin D-SUB, female (body = female and pins = male) connector (DB-9S) to the serial interface on the Main Unit rear panel. Fixing screws for this connector have an inch thread.

1.2 Input/Output Signals

PIN	SIGNAL NAME	FLOW DIRECTION
1		
2	Receive Data (RxD)	IN (From Host to SF)
3	Transmit Data (TxD)	OUT (To Host from SF)
4	Data Terminal Ready (DTR)	OUT (To Host from SF)
5	Signal Ground (SG)	
6	Data Set Ready (DSR)	IN (From Host to SF)
7	Request to Send (RTS)	OUT (To Host from SF)
8	Clear to Send (CTS)	IN (From Host to SF)
9		

Table C-1: RS-232C Pin Assignment

1.3 Communication Format

Asynchronous Half Duplex Mode

1.4 Baud Rate/Character Structure

Setting program "Settings" - "Output Condition" - "HC Setting" has to be executed to set the interface parameters. Underlined items are selected as a default configuration.

Baud Rate	600	1200	2400	4800	9600
Code	7-Bit	8-Bit			
Stop Bit	1-Bit	2-Bit			
Parity Bit	None	Even	Odd		
Class	Class A	Class B			
Interval	0	2	3	5	7	10	15
Sampler No.	12 Digits	13 Digits			
RDW Output	RDW-SD+RDW-CV	RDW-SD	RDW-CV		
PDW Output	Transmit	Not Transmit			
P-LCR Output	Transmit	Not Transmit			

Table C-2: Host Computer Settings

1.5 Signal Level

Signal level of the RS-232C conforms to the EIA RS-232C V.24 standard.

LEVEL	BINARY STATE	FUNCTION
+3 V or Higher	Logic "0", Start Bit	ON
-3 V or Lower	Logic "1", Stop Bit	OFF

Table C-3: RS-232C Signal Level

1.6 Interface Circuit

(1) Output Circuit

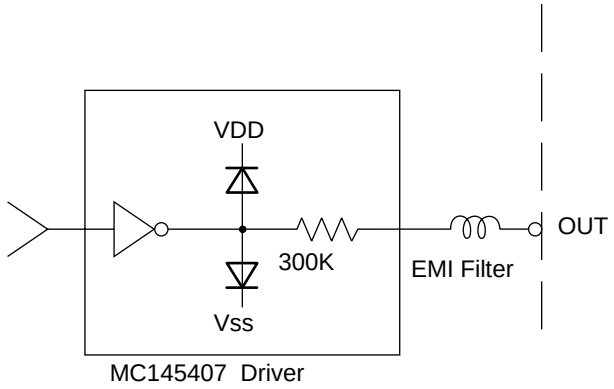


Figure C-1: Interface Output Circuit

(2) Input Circuit

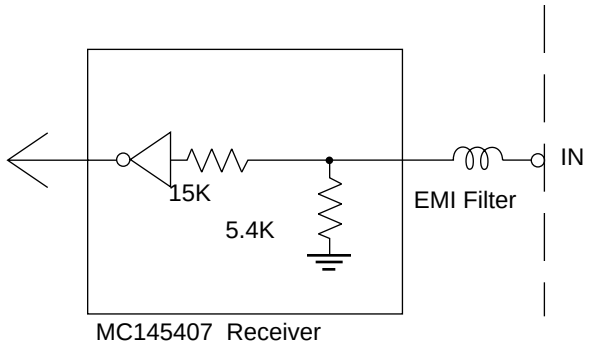


Figure C-2: Interface Input Circuit

1.7 Software

1. Code
   ASCII codes are used in this interface.

2. General Function

FUNCTION	DESCRIPTION
1. Analysis data output	Auto Out -- The SF-3000 automatically sends out analysis data after each analysis has been completed.
	Stored Data -- The SF-3000 sends out data from the stored data in a batch.
2. Inquiry (output) and settings from host computer (input)	When SF-3000 inquires order information by the Rack No. and Tube Position No., the host computer gives order information and the sample ID number for each sample in the rack to SF-3000.

Table C-4: General Functions

3. Framing of Text

   STX (02 in hexadecimal code) is sent prior to data and ETX (03 in hexadecimal code) is sent following data. The text length is within 255 bytes.

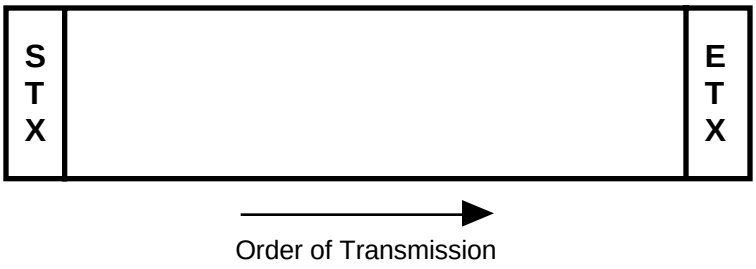


Figure C-3: Order of Transmission

4. Transmission Procedure (One-way communication from SF-3000 to Host)
Two classes are prepared and can be selected. Refer to *Chapter 11: System Setup* for additional information. The factory configuration is Class B and the interval time is 2 seconds.

(1) Class A -- Data is transmitted in the form of a text or blocks. The host computer checks the start and end characters as well as the parity bit received after each character, but does not transmit any response. Therefore, the SF-3000 will not wait for the response ACK (06 in hexadecimal) or NAK (15 in hexadecimal) from the host computer and transmits data to the host computer in one direction with two control signals (CTS and DSR) only.

(2) Class B -- This class is identical to Class A except the receiving side. When the host computer receives transmitted data, the host computer transmits a response followed by a sequence. If necessary the host computer also checks the contents of the text (or block). The SF-3000 waits for the response ACK or NAK from the host computer in addition to two control signals (CTS and DSR) and transmits the next sample data upon receiving ACK from the host computer.

(3) Transmission Error -- If the SF-3000 detects an error after transmitting data, an error message is displayed and transmission of data is terminated. The customer has to resolve the following error status to transmit data.

(a) DSR is OFF,
(b) CTS does not become ON within 5 seconds after entering a command to transmit data to host computer,
(c) SF-3000 receives no response of either ACK or NAK within 15 seconds after transmitting data, or
(d) SF-3000 receives NAK after three retries.

NOTE: Error (c) or (d) occurs only when the Class B is utilized. HC flashes when error (a) or (b) occurs and HC flashes in reverse video when error (c) or (d) occurs.

(4) Interval Time -- Time interval between two data transmitted to the host computer can be selected with the setting program. The interval time means the period after the SF-3000 received the response of ACK/NAK from the host computer until the SF-3000 starts transmission of the next sample data in the Class B.

5. Transmission Protocol (Two-way communication)
Transmission Protocol should be fixed in Class B to inquire order information to the host computer. Selecting Class A will lead to an incorrect communication without showing an error message.

(1) The SF-3000 inquires the order information and receives order information text from the host computer in the following sequence;

(a) The SF-3000 sends order inquiry text to the host computer.

(b) The host computer verifies the received data and responds by sending NAK when an error exists. When no error exists, host computer sends ACK and the order information text that was inquired.

(c) If the SF-3000 receives NAK from the host computer, SF-3000 re-sends the inquiry text. If the SF-3000 receives ACK, SF-3000 verifies the following order information text and sends NAK when an error exists. When no error exists, SF-3000 sends ACK to the host computer.

(d) If the host computer receives ACK from the SF-3000, the host computer completes the communication of order information for one sample. If NAK is received from the SF-3000, the host computer re-sends the order information text to the SF-3000.

SF-3000		Host Computer
Order inquiry text	→	
Resend order inquiry up to 3 times when receiving NAK	←	• ACK when detecting no error in order inquiry transmission • NAK when detecting an error in order inquiry transmission
	←	Order information for the inquired sample
• ACK when detecting no error in order information transmission • NAK when detecting an error in order information transmission	→	Resend order information up to 3 times when receiving NAK

(2) Transmission Error -- If the SF-3000 detects an error after transmitting data, an error message is displayed and transmission of data is terminated. The operator has to resolve the following error status to correctly transmit the data.

(a) DSR is OFF,
(b) CTS does not become ON within 5 seconds after entering a command to transmit data to the host computer,
(c) SF-3000 receives no response of either ACK or NAK within 15 seconds after transmitting data, or
(d) SF-3000 receives NAK after three retries.

> **NOTE:** Error (c) or (d) occurs only when the Class B is utilized. HC flashes when error (a) or (b) occurs and HC flashes in reverse video when error (c) or (d) occurs.

(3) Interval Time -- Time interval between two data transmitted from the host computer can be selected with the setting program. This setting is commonly used for the data transmission to and from the host computer. The interval time means the period after the SF-3000 received the order information from the host computer and transmitting the response of ACK/NAK to the host computer until the SF-3000 receives transmission of the next sample data in the Class B.

6. Order Inquiry Procedure (for Closed Mode Only)

One procedure is prepared to inquire the order information.

Inquiry by Tube Position
The SF-3000 inquires, the order information, of the host computer using the Tube Position No. 1 through 10 as soon as the Rack No. is entered in "Work List" - "Download List" - "From HC" program (batch inquiry). In this case, the key words will be Rack No. and Tube Position No., and the system analyzes the sample according to the order by position information (Rack No., Tube Pos. No.). There is no time limit for the SF-3000 to receive the order information after transmitting the inquiry to the host computer.

> **NOTE:** When "Auto Output" of the analysis data is setup, there is a possibility that the host computer may not be fast enough to receive the sample data and transmit back the order information before the SF-3000 outputs more data. If this occurs it is recommended that you perform these steps separately.

2. TEXT FORMAT

The SF-3000 instrument transmits (1) Patient Sample Data, (2) Quality Control (QC) Data and (3) Inquiry Data. These data are distinguished by the Text Distinction Code I and Sample Distinction Code. (Text length is different among the transmittable data.)

(a) Text Distinction Code I is "D" for the Patient Sample Data and QC Data, or "R" for the Inquiry Data.
(b) Text Distinction Code II is always "1", since the text length is currently within 255 bytes. In the event when the text length is over 256 bytes, text is divided into two or more blocks. The block sequence is indicated with the respective number in the Text Distinction Code II.
(c) Sample Distinction Code is "U" for the Patient Sample Data or "C" for the QC Data.

2.1 Patient Sample Data Format

NOTE: The number of digits in the ID number could be set either 13 or 12 digits by the Settings program.

(a) The order of transmission is from the top parameter to the bottom. The data sent is the most significant digit first, i.e., left to right. Zero suppression is not performed.

(b) The decimal point is not sent. If necessary, add the decimal point on the host computer side as shown in the example.

(c) Date is transmitted in the form set by the Setting program. Zero suppression is not performed.

(d) Rack No. is the 4 digit number assigned to the rack in a batch of analysis. Zero suppression is not performed. "0000" is transmitted when the manual analysis is performed.

(e) Tube Position No. is the position number in which the sample was placed within a rack. Zero suppression is not performed. "00" is transmitted when the manual analysis is performed.

(f) Sequence No. is the 5-digit serial number of the patient sample data in analyzed order obtained after power on. Zero suppression is not performed.

PATIENT SAMPLE DATA FORMAT -- 234 Bytes
(or 233 bytes with 12 digits Sample ID)

Parameter	No. of Chars.	Example
Text Distinction Code I	1	"D"
Text Distinction Code II	1	"1"
Sample Distinction Code	1	"U"
Month (or Day)	2	
Day (or Month)	2	
Year	2	
Rack No.	4	
Tube Position No.	2	
Sequence No.	5	
ID Information	1	
Sample ID Number	13 (or 12)	
Analysis Information	1	
NEG/POS/ERR Information	1	
POSITIVE (Diff.)	1	
POSITIVE (Morph.)	1	
POSITIVE (Count)	1	
ERROR (Func.)	1	
ERROR (Result)	1	
Order Information	1	
Reserved Flag	1	"0"
Reserved Flag	1	"0"
Reserved Flag	1	"0"
Reserved Flag	1	"0"
Reserved Flag	1	"0"
IP Message Information	6	
WBC (x 10^3/µL)	6	(XXX.XXF)
RBC (x 10^6/µL)	5	(XX.XXF)
HGB (g/dL)	5	(XXX.XF)
HCT (%)	5	(XXX.XF)
MCV (fL)	5	(XXX.XF)
MCH (pg)	5	(XXX.XF)
MCHC (g/dL)	5	(XXX.XF)
PLT (x 10^3/µL)	5	(XXXXF)
LYMPH% (%)	5	(XXX.XF)
MONO% (%)	5	(XXX.XF)
NEUT% (%)	5	(XXX.XF)
EO% (%)	5	(XXX.XF)
BASO% (%)	5	(XXX.XF)
LYMPH# (x 10^3/µL)	6	(XXX.XXF)
MONO# (x 10^3/µL)	6	(XXX.XXF)
NEUT# (x 10^3/µL)	6	(XXX.XXF)
EO# (x 10^3/µL)	6	(XXX.XXF)
BASO# (x 10^3/µL)	6	(XXX.XXF)
RDW-CV (%)	5	(XXX.XF)
RDW-SD (fL)	5	(XXX.XF)
PDW (fL)	5	(XXX.XF)
MPV (fL)	5	(XXX.XF)
P-LCR (%)	5	(XXX.XF)
Reserved 1	5	
Reserved 2	5	
Reserved 3	5	
Reserved 4	5	
Reserved 5	5	
Reserved 6	5	
Reserved 7	5	
Reserved 8	5	
Reserved 9	5	
Reserved 10	5	
Reserved 11	5	
Reserved 12	5	

(g) ID information indicates how the sample ID number was entered or read.

"0": The sample ID number was entered manually or the sequential number was applied to the sample ID number in the Manual mode or the Manual Closed mode.
"1": The sequential number was applied to the sample ID number in the Auto mode.
"2": The sequential number was applied to the sample ID number due to the failure in reading the bar code label. This sequential number is reset to 1 when the power is turned on or the power supply is interrupted.
"3": Not used.
"4": The sample ID number was read from the bar code label, or specified by the workload list.
"5": The sequential number was applied to the sample ID No. in Capillary mode.

(h) Sample ID number consists of 13 digits including a hyphen "–" (2D in hexadecimal code). Zero suppression is not performed.

(i) Analysis Information indicates the analysis status of the sample.

"0": Analysis error did not occur.
"1": Analysis error occurred.

(j) NEG/POS/ERR information indicates the flag for the sample as follows:

"0": The sample is flagged NEGATIVE.
"1": The sample is flagged POSITIVE.
"2": The sample is flagged only ERROR.
"3": The sample is flagged both POSITIVE and ERROR.
"Q": The sample is Quality Control material.

(k) POSITIVE (Diff.), POSITIVE (Morph.), POSITIVE (Count), ERROR (Func.), or ERROR (Result) indicates if the sample is flagged, respectively.

"0": The sample is not flagged.
"1": The sample is flagged.

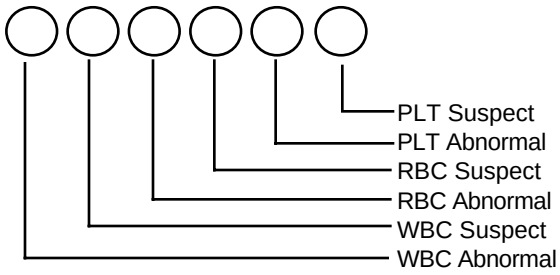
(l) Order Information indicates if the order information exists at the time of sample analysis.

"0": The order information does not exist.
"1": The order information exists.

(m) Reserved Flag -- (Not used and "0" is transmitted.)

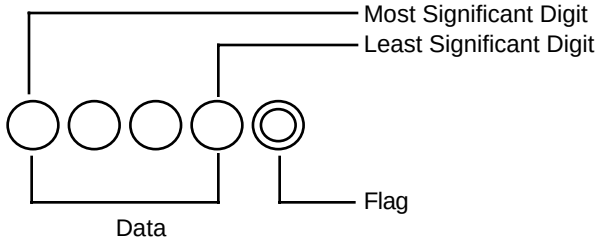
(n) IP Message Information indicates if the WBC, RBC, and PLT parameters are flagged with Abnormal or Suspect IP Messages.

"0": No flag.
"1": Flagged.



(o) "X" in the table indicates the numeric value and "F" in the table indicates the flag code. Zero suppression is not performed. The flag code indicates the following:

"0": The analysis data is within the preset Mark Limits.
"1": The analysis data is greater than the preset Upper Mark Limit.
"2": The analysis data is less than the preset Lower Mark Limit.
"3": The analysis data exceeds the linearity limit.
"4": The analysis data is less reliable due to the abnormality of the blood sample itself.



(p) In case that the analysis data is reported "****", "++++" or " - - - -" with overflow error, with analysis error, or with some flagging, an asterisk mark (*) will be placed in front of the most significant digit and remaining four or five digits will be turned to 0 (zero), thus "*0000" will be sent for the analysis result. If the sample was not analyzed according to the order information, four or five blank spaces will be sent " ".

(q) Reserve 1 through 12 -- (Not used)

2.2 Quality Control Data Format

(a) QC File Information indicates the file number to correspond to each QC files in the $\overline{X}$ or L-J Control or $\overline{X}$ M Control, as shown below.

"1": $\overline{X}$ or L-J Control File No. 1
"2": $\overline{X}$ or L-J Control File No. 2
"3": $\overline{X}$ or L-J Control File No. 3
"4": $\overline{X}$ or L-J Control File No. 4
"5": $\overline{X}$ or L-J Control File No. 5
"6": $\overline{X}$ or L-J Control File No. 6
"7": $\overline{X}$ or L-J Control File No. 7
"8": $\overline{X}$ or L-J Control File No. 8
"9": $\overline{X}$ or L-J Control File No. 9
"A": $\overline{X}$ or L-J Control File No. 10
"B": $\overline{X}$ or L-J Control File No. 11
"C": $\overline{X}$ or L-J Control File No. 12
"M": $\overline{X}$ M Control File

(b) The other parameters are the same as those for the Patient Sample Data Format.

QUALITY CONTROL DATA FORMAT -- 142 Bytes

Parameter	No. of Chars.	Example
Text Distinction Code I	1	"D"
Text Distinction Code II	1	"1"
Sample Distinction Code	1	"C"
QC File Information	1	
Month (or Day)	2	
Day (or Month)	2	
Hour	2	
Minute	2	
RBC (x $10^6/\mu L$)	4	(XX.XX)
HGB (g/dL)	4	(XXX.X)
HCT (%)	4	(XXX.X)
MCV (fL)	4	(XXX.X)
MCH (pg)	4	(XXX.X)
MCHC (g/dL)	4	(XXX.X)
RDW-SD (fL)	4	(XXX.X)
RDW-CV (%)	4	(XXX.X)
PLT (x $10^3/\mu L$)	4	(XXXX)
PDW (fL)	4	(XXX.X)
MPV (fL)	4	(XXX.X)
P-LCR (%)	4	(XXX.X)
WBC (x $10^3/\mu L$)	5	(XXX.XX)
NEUT% (%)	4	(XXX.X)
LYMPH% (%)	4	(XXX.X)
MONO% (%)	4	(XXX.X)
EO% (%)	4	(XXX.X)
BASO% (%)	4	(XXX.X)
NEUT# (x $10^3/\mu L$)	5	(XXX.XX)
LYMPH# (x $10^3/\mu L$)	5	(XXX.XX)
MONO# (x $10^3/\mu L$)	5	(XXX.XX)
EO# (x $10^3/\mu L$)	5	(XXX.XX)
BASO# (x $10^3/\mu L$)	5	(XXX.XX)
Reserved 1	5	
Reserved 2	3	
GRAN-X	4	(XXX.X)
GRAN-Y	4	(XXX.X)
WBC/BA-X	4	(XXX.X)
WBC/BA-Y	4	(XXX.X)
GRAN-Y (W)	4	(XXX.X)
Reserved 3	4	(XXX.X)

2.3 Inquiry Data Format

(a) Text Distinction Code I is "R".

(b) Inquiry Mode
"1": (Not Used)
"2": Batch Inquiry, using the Rack No. and Tube Position No.

(c) Sample ID No.
(Not Used)

(d) Rack No. is a 4-digit number assigned to a rack in a batch analysis. This becomes valid only when the batch inquiry is performed. Zero suppression is not performed.

(e) Tube Position No. is the position number in which the sample is placed within a rack. This becomes valid only when the batch inquiry is performed. Zero suppression is not performed.

INQUIRY DATA FORMAT -- 21 Bytes

Parameter	No. of Chars.	Example
Text Distinction Code I	1	"R"
Inquiry Mode	1	
Sample ID No.	13	
Rack No.	4	
Tube Position No.	2	

2.4 Order Information Data Format

(a) Text Distinction Code I is "S".

(b) Information Status indicates if the order information has been registered.

"0": Order information has not been registered.
"1": Order information has been registered.
"2": Order is for the Quality Control purpose.

(c) Date Ordered indicates the date of order in the format of "yyyymmdd" in the Christian Era (A.D.), where "yyyy" is the year, "mm" is the month and "dd" is the day. Zero suppression is not performed.

(d) Sample ID No. consists of 13 digits including a hyphen "–" (2D in hexadecimal code). Zero suppression is not performed. The sample ID No. is assigned for the sample placed in the Rack at the Tube Position No. when the batch inquiry is performed using the Rack No. and Tube Position No. When the sample is the Quality Control material, either of the following two assignment methods can be used: "000000000QCxx" where xx represents the QC file No. 01 through 12, or "00QC-xxxxxxxx" where xxxxxxxx represents the Lot No. of the SF-CHECK.

(e) Rack No. is a 4-digit number assigned to a rack in a batch analysis. Zero suppression is not performed. This becomes identical to the Inquiry Data Format when the batch inquiry is performed using the Rack No. and Tube Position No.

(f) Tube Position No. is the position number in which the sample is placed within a rack. Zero suppression is not performed. This becomes identical to the Inquiry Data Format when the batch inquiry is performed using the Rack No. and Tube Position No.

(g) Inquiry Mode

"1": (Not Used)
"2": Batch Inquiry, using the Rack No. and Tube Position No.

(h) Order Information for each Parameter

"0": Do not analyze
"1": Analyze

ORDER INFORMATION DATA FORMAT -- 171 Bytes

Parameter	No. of Chars.	Example
Text Distinction Code I	1	"S"
Information Status	1	
Date Ordered	8	"yyyymmdd"
Sample ID No.	13	
Rack No.	4	
Tube Position No.	2	
Inquiry Mode	1	
Reserved 1	13	
Reserved 2	25	
Reserved 3	1	
Reserved 4	8	
Reserved 5	15	
Reserved 6	8	
Reserved 7	40	
WBC	1	
RBC	1	
HGB	1	
HCT	1	
MCV	1	
MCH	1	
MCHC	1	
PLT	1	
LYMPH%	1	
MONO%	1	
NEUT%	1	
EO%	1	
BASO%	1	
LYMPH#	1	
MONO#	1	
NEUT#	1	
EO#	1	
BASO#	1	
RDW-CV	1	
RDW-SD	1	
PDW	1	
MPV	1	
P-LCR	1	
Reserved 8	1	
Reserved 9	1	
Reserved 10	1	
Reserved 11	1	
Reserved 12	1	
Reserved 13	1	
Reserved 14	1	
Reserved 15	1	

3. ID BAR CODE

3.1 Applicable Bar Codes

The types of bar codes acceptable to the SF-3000 and the relation of the check-digit to each bar-code type are as follows:

(1) Sample ID No.

Type of Bar-Code	Check-Digit	No. of Digits for Sample ID No.	No. of Digits for Check-Digit
NW-7 (CODABAR)*	Not Used	1 - 13 digits	Not Applied
	Modulus 11	1 - 13 digits	1 digit
	W. Modulus 11	1 - 13 digits	1 digit
	Modulus 16	1 - 13 digits	1 digit
CODE-11	Code 11	1 - 13 digits	1 digit
CODE-39	Not Used	1 - 13 digits	Not Applied
	Modulus 43	1 - 13 digits	1 digit
CODE-128	Modulus 103	1 - 13 digits	1 digit
ITF (Interleaved 2 of 5)	Not Used	1 - 13 digits	Not Applied
	Modulus 10	1 - 13 digits	1 digit
JAN-8	Modulus 10	7 digits	1 digit
JAN-13	Modulus 10	12 digits	1 digit

*: Start and Stop code can be any one of the characters "A", "B", "C", "a", "b" and "c".

(2) Rack ID No.

Type of Bar-Code	Check-Digit	No. of Digits for Rack ID No.	No. of Digits for Check-Digit
NW-7 (CODABAR)*	Modulus 16	4 digits	1 digit

*: Start and Stop code can be any one of the characters "D" and "d".

3.2 Dimensions of Elements

Bar codes consists of five elements: a narrow bar, a narrow space, a wide bar, a wide space, and a gap between characters. Each element has to comply with all of these equations:

(a) Narrow element ≥ 150 µm
(b) Wide element ≤ 1.2 mm
(c) Narrow element ≤ Gap between characters ≤ Wide element

NOTE: ITF does not require above mentioned item (c), since ITF does not use a gap between characters.

3.3 Requirements on Wide/Narrow Ratio

For each character, the ratio of the wide element and the narrow element has to comply with all the equations listed below:

(1) $\frac{\text{Narrow (Max)}}{\text{Narrow (Min)}} \leq 1.3$

(2) $\frac{\text{Wide (Min)}}{\text{Narrow (Max)}} \geq 2.2$

(3) $\frac{\text{Wide (Max)}}{\text{Wide (Min)}} \leq 1.4$

Here, the narrow (Max) means the widest element of narrow elements in a character. The narrow (Min) means the narrowest element of narrow elements in a character. The wide (Min) means the narrowest element of the wide elements in a character and the wide (Max) means the widest element of wide elements in a character.

3.4 Optical Requirements

(1) Requirement on the Print Contrast Signal (PCS) is:

$$PCS = \frac{Rs-Rb}{Rs} \geq 0.6$$

Rs: the reflectivity of the space (background)
Rb: the reflectivity of the black inked bar

The measuring method conforms to the *JIS (Japanese Industrial Standards) B9550, "5.3 Optical Characteristics of Bar Code Symbols"*.

(2) Reflective characteristics of the label surface

The bar code reader defines the white and black by the reflected light intensity when the light is applied to the label at an angle of approximately 25°. Therefore, most of the reflection of the label surface should be diffused reflection. For example, a laminated label may cause specular reflection, which will increase the reflection directivity too much and cause the ID reader to miss scan lines. See the following figures.

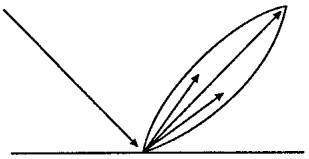


Figure C-4: Specular Reflection

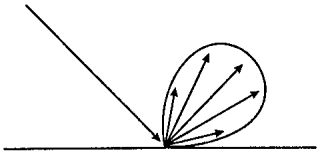


Figure C-5: Diffused Reflection

(3) Irregularity and roughness of the printing

When a bar element is magnified, the following may be observed. The variation coefficient (S) in the width of a bar should be less than or equal to 20%.

$$S(\%) = \frac{\text{Max-Min}}{\text{Max}} \times 100$$

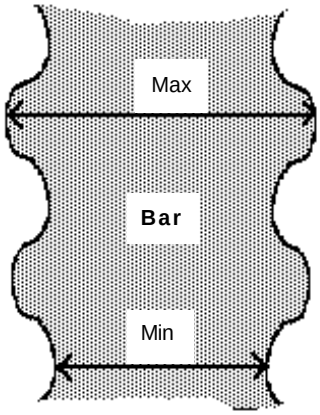


Figure C-6: Magnified Bar

3.5 Dimensions of Bar Code Label

When each part of the label is named as in Figure C-7 below:

(a) The leading and trailing spaces should be greater than or equal to 2.5 mm.

(b) The effective length of bars should be less than or equal to 40 mm. This length is related to the ease of placing the label. The physical absolute maximum length is 48 mm.

(c) The bar height should be greater than or equal to 20 mm. This height is theoretically required to be at least 5 mm to scan lines. However, a label of which bar height is only 5-10 mm may cause problems as the tube may rotate to sufficiently prevent the instrument from reading the bar code.

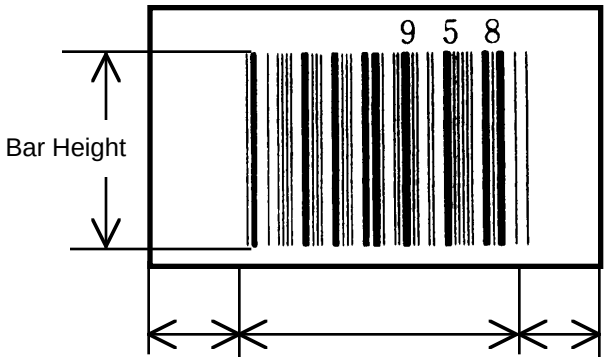


Figure C-7: Bar Code Label

3.6 Check-Digit

The bar code ID system requires the check-digit(s) to be added on the bar code label to improve the reliability of the ID number.

(A) Modulus 10/Weight 3

This Modulus 10/Weight 3 method is used in the bar code symbology such as JAN/EAN/UPC and ITF (Interleaved 2 of 5). Check digit computation method is shown as follows;

(1) The least significant digit (right most digit) and all digits that occur on the odd position from right to left within the data digits are defined as odd digits. All the digits are divided into two groups, odd digits and even digits.

(2) Add all odd digits. Multiply the sum by 3.

(3) Add all even digits.

(4) Add the result of (2) and result of (3) above.

(5) Subtract the foremost digit from 10 to obtain the check-digit. In case of the ITF, the total number of the digits must be an even number. In such case, append "0" to the most significant digit (left most digit).

Example No. 1:
Calculation of the check-digit for the JAN code 4912345 (7 digits) is shown below:

(1) Add odd digits: 5+3+1+4 = 13.
Multiplied the sum by 3, as: 13 x 3 = 39

(2) Add even digits: 4+2+9 = 15

(3) Add the results of (1) and (2) above, as: 39+15 = 54

(4) Check-digit is obtained by subtracting the right most digit of the sum of (3) above from 10 as: 10-4 = 6
Hence the check-digit is 6.

Example No. 2:
Calculation of the check-digit for the ITF code 524362 (6 digits) is shown below:

(1) Add odd digits : 2+3+2 = 7.
Multiplied the sum by 3, as: 7 x 3 = 21

(2) Add even digits: 6+4+5 = 15

(3) Add the results of (1) and (2) above, as: 21+15 = 36

(4) Obtain the check-digit as: 10-6 = 4
Hence the check-digit is 4.

However, in Example No. 2, the sum of the total number of the data digits and the check-digit gives odd number 7 in this case. Therefore, "0" is prepended to the most significant digit (left most digit) and check-digit is appended to the data, as 05243624.

(B) Modulus 11

This Modulus 11 method is used in the bar code symbology such as CODE-11, NW-7 and CODABAR. Check digit computation method is shown as follows:

The following example uses the ID number 15-2345-6789.

(1) Weight is multiplied to each digit as:

ID Number	1	5	-	2	3	4	5	-	6	7	8	9
	x	x	x	x	x	x	x	x	x	x	x	x
Weight	3	2	1	10	9	8	7	6	5	4	3	2
	3	10	0	20	27	32	35	0	30	28	24	18

The weight of the ID number is 3, 2, 1, ... 6, 5, 4, 3, 2 is applied to each one from the least significant to the most significant digit. The position of the check-digit is in the least significant digit of the ID number and its weight is 1.

(2) Add each product as given below:

Sum = 3+10+0+20+27+32+35+0+30+28+24+18 = 227

(3) Divide the sum by 11 and get the remainder. Then subtract the remainder from 11. The result will be the check-digit.

227/11 = 20; remainder = 7,
11-7 = 4,
Hence the check-digit is 4.

Note that all symbols except the numbers are calculated as zero(0). The check-digit will be zero (0) when the resulted check-digit is 10 or 11.

(4) This check digit is appended to the ID number;
the bar code label is now 15-2345-67894.

(5) When the ID Reader reads this bar code label, the instrument computes the check-digit(s) and recognizes the read as a valid read if the remainder is 0 or 1.

(C) Weighted Modulus 11

This Weighted Modulus 11 method is used in the bar-code symbology such as NW-7 and CODABAR. Check-digit computation method is shown as follows:

The following example uses the ID number 15-2345-6789.

(1) Weighted Modulus-11 has two sets of the weight:

The first weight set is 2, 6, 3, 5, 4, 8, 7, 10, 9, 5, 3, 6
The second weight set is 9, 5, 8, 6, 7, 3, 4, 10, 2, 6, 8, 5
Each digit is applied to one digit of the ID number, from the least significant to the most significant digit. The second weight set is used when the check digit is computed to "10" as the result of using the first weight set. All symbols are assumed 0 (zero) in the calculation. Therefore, the first weight set is multiplied to each digit as given below:

ID Number	1	5	-	2	3	4	5	-	6	7	8	9
	x	x	x	x	x	x	x	x	x	x	x	x
Weight	6	3	5	9	10	7	8	4	5	3	6	2
	6	15	0	18	30	28	40	0	30	21	48	18

(2) Add each product as given below:

Sum=6+15+0+18+30+28+40+0+30+21+48+18=254

(3) Divide the sum by 11 and get the remainder. Then subtract the remainder from 11. The result will be the check-digit.

254/11 = 23; remainder = 1,
11-1 = 10,
The check-digit is now computed by using the second weight set as:

ID Number	1	5	-	2	3	4	5	-	6	7	8	9
	x	x	x	x	x	x	x	x	x	x	x	x
Weight	5	8	6	2	10	4	3	7	6	8	5	9
	5	40	0	4	30	16	15	0	36	56	40	81

(4) Add the each product as given below:

Sum=5+40+0+4+30+16+15+0+36+56+40+81 = 323

(5) Divide the sum by 11 and get the remainder. Then subtract the remainder from 11. The result will be the check-digit.

323/11 = 29; remainder = 4,
11-4 = 7,
Hence the check-digit is 7.

(6) This check digit is appended to the ID number;
the bar-code label is now 15-2345-67897.

(7) When the ID Reader reads this bar code label, the instrument computes the check-digit by using the first weight set and recognizes the read as a valid read if the remainder is 0. If the remainder is not 0, the instrument computes the check-digit by using the second weight set and recognizes the read as a valid read if the remainder is 0.

(D) Modulus 16

The Modulus 16 is the check-digit computation method used in the NW-7 and CODABAR symbologies. Since the NW-7 and CODABAR symbologies use 4 kinds of start/stop codes, these start/stop codes are computed from the data digits.

The following example uses the ID number D998147D.

(1) Add the values of all the data characters including the start and stop codes. The numerical value of each of the data character is given below:

Character	Value	Character	Value	Character	Value
0	0	7	7	.	14
1	1	8	8	+	15
2	2	9	9	A	16
3	3	–	10	B	17
4	4	$	11	C	18
5	5	:	12	D	19
6	6	/	13		

Sum = 19+9+9+8+1+4+7+19 = 76

(2) Divide the sum by 16 and get the remainder. Then subtract the remainder from 16. The result is the check-digit. When the remainder is 0, check-digit becomes 16. In such a case set the check-digit to "0".

76/16 = 4; remainder = 12,
16-12 = 4,
Hence the check-digit is 4.

(3) This check-digit is appended to the left of the stop code in the ID number; the bar code label is now D9981474D.

(4) When the ID Reader reads this bar code label, the instrument computes the check-digit and recognizes the read as a valid read if the remainder is 0.

(E) Modulus 43

Modulus 43 is the check digit computation method used in the CODE-39 symbology. Each of 43 characters is assigned each value. All characters are converted into the value and computed.

The following example uses the ID number **258-416**.

(1) Add the values of all the data characters. The numerical value of each of the data characters is given below:

Character	Value	Character	Value	Character	Value
0	0	F	15	U	30
1	1	G	16	V	31
2	2	H	17	W	32
3	3	I	18	X	33
4	4	J	19	Y	34
5	5	K	20	Z	35
6	6	L	21	–	36
7	7	M	22	.	37
8	8	N	23	Space	38
9	9	O	24	$	39
A	10	P	25	/	40
B	11	Q	26	+	41
C	12	R	27	%	42
D	13	S	28		
E	14	T	29		

Sum = 2+5+8+36+4+1+6 = 62

(2) Divide the sum by 43 and get the remainder.

62/43 = 1; remainder = 19

(3) Find the check-character. The check-character is that character whose value is equal to the remainder. In this example, the letter "J" has the value of 19 which is equal to the remainder. Therefore "J" is the check-character.

(4) This check-character is appended to the ID number, after the least significant digit. The bar-code label is now "258-416J".

(F) Modulus 103

Modulus 103 is the check-digit computation method used in the CODE-128 symbology. CODE-128 takes three different character table depending on the start code. Each of 128 characters is assigned a value as shown in the following table. All characters are then converted to their corresponding values and computed.

(1) All characters except the stop code are converted to their corresponding values according to the table.

(2) The first character, such as "Start (Code A)", indicates that the Code A set is used until other code set is specified. Multiply the most significant digit by 1, multiply the second digit by 2, multiply the third digit by 3, and so on.

(3) Add all the products.

(4) Divide the sum by 103.

(5) Convert the remainder to the corresponding character in the table. This is the check-digit.

The following example uses the ID number **Start (Code A) 123-4567**.

(1) Convert each character into values using Code A set, and multiply by the weight.

Start (Code A) 103 = 103
1 17 x 1 = 17
2 18 x 2 = 36
3 19 x 3 = 57
- 13 x 4 = 52
4 20 x 5 = 100
5 21 x 6 = 126
6 22 x 7 = 154
7 23 x 8 = 184

(2) The sum of the products is 829.

(3) This sum is divided by 103 as; 829/103 = 8 and remainder is 5.

(4) The corresponding character for the value 5 is %. Hence the check-digit is %.

Value	Code A	Code B	Code C	Value	Code A	Code B	Code C
0	(space)	(space)	00	54	V	V	54
1	!	!	01	55	W	W	55
2	"	"	02	56	X	X	56
3	#	#	03	57	Y	Y	57
4	$	$	04	58	Z	Z	58
5	%	%	05	59	[	[	59
6	&	&	06	60	\	\	60
7	'	'	07	61	]	]	61
8	(	(	08	62	^	^	62
9	)	)	09	63	_	_	63
10	*	*	10	64	NUL	`	64
11	+	+	11	65	SOH	a	65
12	,	,	12	66	STX	b	66
13	-	-	13	67	ETX	c	67
14	.	.	14	68	EOT	d	68
15	/	/	15	69	ENQ	e	69
16	0	0	16	70	ACK	f	70
17	1	1	17	71	BEL	g	71
18	2	2	18	72	BS	h	72
19	3	3	19	73	HT	i	73
20	4	4	20	74	LF	j	74
21	5	5	21	75	VT	k	75
22	6	6	22	76	FF	l	76
23	7	7	23	77	CR	m	77
24	8	8	24	78	SO	n	78
25	9	9	25	79	SI	o	79
26	:	:	26	80	DLE	p	80
27	;	;	27	81	DC1	q	81
28	<	<	28	82	DC2	r	82
29	=	=	29	83	DC3	s	83
30	>	>	30	84	DC4	t	84
31	?	?	31	85	NAK	u	85
32	@	@	32	86	SYN	v	86
33	A	A	33	87	ETB	w	87
34	B	B	34	88	CAN	x	88
35	C	C	35	89	EM	y	89
36	D	D	36	90	SUB	z	90
37	E	E	37	91	ESC	{	91
38	F	F	38	92	FS	|	92
39	G	G	39	93	GS	}	93
40	H	H	40	94	RS	~	94
41	I	I	41	95	US	DEL	95
42	J	J	42	96	FNC3	FNC3	96
43	K	K	43	97	FNC2	FNC2	97
44	L	L	44	98	SHIFT	SHIFT	98
45	M	M	45	99	CODE C	CODE C	99
46	N	N	46	100	CODE B	FNC4	CODE B
47	O	O	47	101	FNC4	CODE A	CODE A
48	P	P	48	102	FNC1	FNC1	FNC1
49	Q	Q	49	103	START (Code A)		
50	R	R	50	104	START (Code B)		
51	S	S	51	105	START (Code C)		
52	T	T	52		STOP		
53	U	U	53				

3.7 Applicable Characters

The valid characters for the ID bar code system are numerals (0-9) and a hyphen (-). CODABAR (NW-7) and CODE-39 may use the other characters such as alphabets. The SF-3000 ID system does not recognize them. The ID number allows up to thirteen digits. The application of hyphens in an ID number should adhere to the following rules:

(1) Hyphens must be placed between other characters.
(2) The ID number cannot begin or end with a hyphen.
(3) Hyphens are included as part of the allowable maximum number of 13 characters.
(4) When calculating check character of an ID number that includes hyphens, the hyphen in CODABAR (NW-7) is calculated as 0 (zero), and hyphen in CODE-11 is calculated as 10 in decimal. In the CODE-39 symbology, the hyphen is calculated as 0 (zero) for Modulus 11, and as 36 for Modulus 43.
(5) ITF cannot recognize the hyphen since this symbology does not allow such a character.

3.8 Effective Bar Code Length

For the NW-7 (CODABAR) and CODE-39 symbologies, the ID number can consist a minimum of 1 digit, and a maximum of 13 digits. For the other symbologies, the minimum number of digits depends on the symbology used and the application of the check-digit.

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